ESTTA Tracking number: **ESTTA533245**

Filing date: **04/19/2013**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91205081
Party	Defendant Dynamic Sports Nutrition, LLC
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Submission	Motion for Summary Judgment
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Date	04/19/2013
Attachments	2259-36 Applicant's Second MSJ.pdf (78 pages)(7382805 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Trademark Application No. 85/340,058
Published in the Official Gazette on January 10, 2012

Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.),	§	
Opposer,	§	Opposition No. 91205081
v.	§	
Dynamic Sports Nutrition, LLC,	§	
Applicant.	§	

APPLICANT'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and TBMP § 528, Dynamic Sports Nutrition, LLC ("Applicant") respectfully moves the Court for entry of summary judgment on the claims of deceptiveness, deceptive misdescriptiveness, and false suggestion of a connection, and dismiss the Opposition filed by Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.) ("Opposer") against the "DECA-DURABOLIN" mark, U.S. App. Serial No. 85/340,058 ("'058 application"). Summary judgment and dismissal of the Opposition are proper in this proceeding because there is no genuine issue of fact, and because Applicant is entitled to judgment as a matter of law. In this case, Applicant's "DECA-DURABOLIN" mark is not descriptive and therefore, as a matter of law, cannot be a deceptive or deceptively misdescriptive mark. In addition, Applicant's "DECA-DURABOLIN" mark is not the same as, or a close approximation of, the Opposer's previously used "name" or "identity", i.e. Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.), and therefore, as a matter of law, cannot falsely suggest a connection with Opposer.

This Motion for Summary Judgment is submitted prior to the commencement of Opposer's testimony period and is based on the attached Memorandum of Law, Declaration of Kevin S. Wilson ("Wilson Decl."), and the exhibits attached thereto. Furthermore, in accordance with the Board's preferred practices, Applicant affirms that Applicant's first Motion for Summary Judgment, which was filed April 17, 2013 and denied as premature, as well as the current Motion for Summary Judgment, have both been timely filed after the parties attended a Discovery Conference on March 26, 2013 and after April 16, 2013, when Applicant served Applicant's Initial Disclosures on counsel for the Opposer. *See Compagnie Gervais Danone v. Precision Formulations LLC*, 89 USPQ2d 1251, 1255 n. 7 (TTAB 2009) (indicating that "if a party moves for summary judgment prior to the deadline for making initial disclosures it should indicate in its motion that the disclosures have been made"); *see also* [Wilson Decl. Ex. I] (attaching a true and correct copy of Applicant's Initial Disclosures served on counsel for the Opposer April 16, 2013, a date which is prior to the date on which Applicant filed its first Motion for Summary Judgment as well as the current Motion for Summary Judgment).

The interests of judicial economy and fairness to both parties are best served by concluding this Opposition proceeding at this time. Therefore, It is respectfully requested that this Motion be granted and that the Opposition be dismissed with Prejudice. Pursuant to Trademark Rule 2.127(d) of the Trademark Rules of Practice it is requested that the proceedings be suspended pending the disposition of this motion.

Respectfully submitted,

April 19, 2013
Date

/2259-36/

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CERTIFICATE OF SERVICE

I hereby certify that Applicant's Motion for Summary Judgment, Memorandum of Law in Support thereof and the Declaration and attached Exhibits are being sent by first class mail on April 19, 2013, to the correspondence of record for Opposer at the following address:

Marie Lavalleye
Hope Hamilton
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ATTORNEY FOR OPPOSER
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Our File: 2259-36

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In the Matter of Trademark Application No. 85/340,058
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Opposer,	§	
v.	§	Opposition No. 91205081
Dynamic Sports Nutrition, LLC,	§	
Applicant.	§	

MEMORANDUM OF LAW IN SUPPORT OF APPLICANT DYNAMIC SPORTS NUTRITION, LLC'S MOTION FOR SUMMARY JUDGMENT

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I. PRELIMINARY STATEMENT

Opposer filed its Notice of Opposition on May 9, 2012. On May 30, 2012 Applicant filed its Rule 12(b) Motion to Dismiss Opposer's Notice of Opposition for Failure to State a Claim. Opposer filed a Reply to the Motion to Dismiss on June 28, 2012 and Applicant filed a Response in Support of the Motion to Dismiss on July 12, 2012. On December 27, 2012 the Board issued an Order Granting, in part, Applicant's Motion to Dismiss. On January 25, 2013 the Opposer filed an Amended Notice of Opposition. Applicant filed its Answer to the Amended Notice of Opposition on February 22, 2013.

II. STATEMENT OF UNDISPUTED FACTS

A. Applicant Dynamic Sports Nutrition, LLC

Opposer Dynamic Sports Nutrition, LLC is a Limited Liability Company organized under the laws of Texas and having an address of 1330 Post Oak Blvd., Ste. 2900, Houston, Texas, 77056. On June 7, 2011, Applicant filed U.S. Trademark Application No. 85/340,058 for the mark "DECA-DURABOLIN".

B. Opposer Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.)

Upon information and belief, Opposer is a Private Limited Liability Company organized under the laws of the Netherlands and has an address of Waarderweg 39, 2031 BN Haarlem, the Netherlands.

III. ARGUMENT

A. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine issues of material fact to be tried and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The Supreme Court has held that the "[s]ummary judgment procedure is properly regarded not as a

disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *see also Sweats Fashions, Inc. v. Pannill Knitting Co.*, 833 F.2d 1560, 1562 (Fed. Cir. 1987). The evidence must be sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party. *First Nat 'I Bank v. Cities Service Co.*, 391 U.S. 253 (1968). Summary judgment is particularly appropriate where, as here, actual testimony is unlikely to address any new or additional evidence which might bear on the critical factual issues or which would reasonably be expected to change the result. *Pure Gold, Inc. v. Syntex (U.S.A.) Inc.*, 222 USPQ 741,743 (Fed. Cir. 1984); *Person's Co., Ltdv. Christman,* 9 U.S.P.Q.2d 1477, 1478 (TTAB 1988), affd, 900 F.2d 1565 (Fed. Cir. 1990).

In the present case, the legal issues are squarely presented. A decision can be made now, because, as a matter of law, the Applicant is entitled to a judgment in its favor. Therefore, "(f)urther litigation in this case not only would put the parties to unnecessary expense but also, equally important, would be wasteful of judicial resources." *Pure Gold Inc. v. Syntex (U.S.A.), Inc.*, 222 USPQ 741, 744 (Fed. Cir. 1984). In *Pure Gold*, the Federal Circuit stated that the routine disposition of cases on motions for summary judgment was to be commended:

> The adoption of similar practice is to be encouraged in inter partes cases before the Trademark Trial and Appeal Board, which seem particularly suitable to this type of disposition. Too often we see voluminous records which would be appropriate to an infringement or unfair competition suit but are wholly unnecessary to resolution of the issue of registrability of a mark.

Id. at 744, n.2.

The Trademark Trial and Appeal Board has repeated the Federal Circuit's decisions in favor of increased use of summary judgment. *See, Nature's Way Products, Inc. v. Nature's Herbs Inc.*,

9 USPQ2d 2077 (TTAB 1989). Similarly, the U.S. Supreme Court has encouraged the use of Summary Judgment. *See, e.g., Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

B. Applicant's Mark Does Not Falsely Suggest a Connection With Opposer.

In an order to prevail on a claim of false suggestion of a connection under Trademark Act Section 2(a), the Opposer must establish four essential elements, namely, (1) the applicant's mark is the same as, or a close approximation of, the opposer's previously used name or identity; (2) it must be established that the applicant's mark would be recognized as such, in that it points uniquely and unmistakably to the opposer; (3) it must be shown that the opposer is not connected with the goods or services provided by the applicant under its mark, and (4) the opposer's name or identity is of sufficient fame or reputation that, when applicant's mark is used on its goods or services, a connection with Opposer would be presumed by someone considering purchasing the goods or services. *See University of Notre Dame du Lac v. J. C. Gourmet Food Imports Co., Inc.*, 703 F.2d 1372 (Fed. Cir. 1983); *see also In re Sloppy Joe's International Inc.*, 43 USPQ2d 1350 (TTAB 1997); *Buffett v. Chi-Chi's, Inc.*, 226 USPQ 428 (TTAB 1985). Furthermore, Opposer must establish proprietary rights in its name or identity which are allegedly prior to the applicant's proprietary rights. *In re Kayser-Roth Corp.*, 29 USPQ2d 1379, 1383 (TTAB 1993); *Kardex Systems, Inc. v. Sistemco N.V.*, 221 USPQ 149, 151 (TTAB 1983).

The Federal Circuit has made it clear that Section 2(a) was designed to protect "the name of an individual or institution which was not a technical 'trademark' or 'trade name' upon which an objection could be made under Section 2(d)." *University of Notre Dame du Lac*, 703 F.2d at 1375 (emphasis added). It is important to bear in mind that Section 2(a) was "not designed primarily to protect the public, but to protect persons and institutions from exploitation of their persona." *In re MC MCS.r.l.*, 88 USPQ2d 1378, n.5 (quoting *Bridgestone/Firestone Research, Inc. v. Automobile*

Club De L'Quest De La France, 245 F.3d 1359 (Fed. Cir. 2001)). As espoused by the Federal Circuit, "the drafters sought by § 2(a) to embrace concepts of the right to privacy . . . . It is a right of this nature to control the use of one's identity". *Id.* at 1376.

In the present case, it is important to note at the outset that Opposer has abandoned its trademark "DECA-DURABOLIN". *See* [Opposer's Amended Notice of Opposition at 3] (standing for the proposition that "Opposer and its affiliated companies do not currently sell products under the DURABOLIN and DECA-DURABOLIN marks in the United States"); *see also* [Wilson Decl. Ex. A, B] (demonstrating that Trademark Registration No. 2,932,737 for the mark "DECA-DURABOLIN" was abandoned October 21, 2011 and Trademark Registration No. 641,324 for the mark "DECA-DURABOLIN" was abandoned May 17, 2003). In addition, the Federal Register contains an entry in which the Food and Drug Administration ("FDA") verifies that Organon notified the FDA in a letter dated May 21, 2002 that it was discontinuing use of its product sold under the mark "DECA-DURABOLIN" in the U.S. *See* [Wilson Decl. Ex. E]. The most recently updated version of the Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations indicates that nandrolone decanoate, sold by Organon USA Inc. under the mark "DECA-DURABOLIN", is currently discontinued. *See* [Wilson Decl. Ex. H]. Upon information and belief, Organon and Organon USA Inc. are predecessors-in-interest to Opposer. Furthermore, there is a plethora of evidence on the internet to support the conclusion that Opposer and its predecessors abandoned the "DECA-DURABOLIN" mark. *See, e.g.*, [Wilson Decl. Ex. D] (indicating that nandrolone decanoate, the generic name for the product sold by Organon under the trademark "DECA-DURABOLIN", is no longer in production) *and* [Wilson Decl. Ex. F] (espousing that on March 20, 2007 Watson abandoned the drug nandrolone decanoate, which is sold under the brand name "DECA-DURABOLIN") *and* [Wilson Decl. Ex. G, pg. 10] (propounding that

"DECA-DURABOLIN" was introduced in the 1960's and began to take a back seat to "DURABOLIN"; the article continues that "DURABOLIN" was not completely abandoned by Organon, as it is sold in select markets, most notably Portugal, India, Malaysia, Indonesia, Netherlands, Finland, and Taiwan; notably, there is no mention of the United States). In short, the "DECA-DURABOLIN" mark has been abandoned by Opposer and its predecessors-in-interest for more than ten years. *See* [Wilson Decl. Ex. E] (standing for the proposition that Organon notified the FDA in a letter dated May 21, 2002 that it was discontinuing use of its product sold under the mark "DECA-DURABOLIN" in the U.S.).

As to the first prong of the test for false suggestion of a connection, Opposer has never previously used the term "DURABOLIN" or "DECA-DURABOLIN" as the "name or identity" of a "person or institution", as the relevant statute has been interpreted by the Federal Circuit. *See University of Notre Dame du Lac*, 703 F.2d at 1375. Since the Opposer has never been identified as "DURABOLIN" or "DECA-DURABOLIN", the relevant public would not consider the phrase "DECA-DURABOLIN" to be considered "synonymous with", and "almost a nickname of" Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.). *See Buffett v. Chi-Chi's, Inc.*, 226 USPQ 428, 430 (TTAB 1985). Similarly, Opposer does not presently have the requisite "proprietary rights in its name or identity which are allegedly prior to the applicant's proprietary rights." Jeffery A. Handelman, *Guide to TTAB Practice* at 8-31 (2011 Supplement).

Opposer appears to postulate that Opposer's proprietary rights in the New Drug Application (NDA) 011891 to sell an injectable anabolic steroid in the United States with the active ingredient of Nandrolone Phenpropionate serves as the basis for Opposer's false suggestion of a connection claim. *See* [Opposer's Amended Notice of Opposition at 6] (positing that Applicant's "DECA-DURABOLIN" trademark application is similar in appearance to the mark that Opposer once used

on NDA 011891). Such an interpretation is clearly at odds with the plain language of the statute, which enumerates that the false suggestion of a connection cause of action exists to protect "persons, living or dead, institutions, beliefs, or national symbols". 15 USC § 1052(a). While Oppposer may very well have proprietary rights to NDA 011891, those proprietary rights exist independent of any rights to the term "DECA-DURABOLIN". This distinction is crucial, because Opposer does not have proprietary rights to the term "DECA-DURABOLIN", as abandoned trademarks are not among the class of persons or institutions protected under the statute. *See* 15 USC § 1052(a).

As explained by Professor McCarthy, under Section 2(a) "Even if a celebrity's trademark rights were abandoned by non-use as a trademark for goods, that person can still prevail under 2(a) if the registered mark falsely suggests a connection with a person." 3 McCarthy on Trademarks § 19:76 at 19-240. However, Professor McCarthy does not give any indication that a party can prevail under 2(a) if a registered mark falsely suggests a connection with an abandoned trademark, because such an interpretation would vitiate the plain language of the statute, eviscerate the legislative intent behind the statute, and violate the Federal Circuit's interpretation of the statute, all of which elucidate that the statute was enacted to protect the "name or identity" of a "person or institution". *See University of Notre Dame du Lac*, 703 F.2d at 1375. If Opposer seeks to protect expired trademark registrations, Opposer should renew such registrations or simply not abandon use of such marks. *See* [Wilson Decl. Ex. E] (standing for the proposition that Organon notified the FDA in a letter dated May 21, 2002 that it was discontinuing use of its product sold under the mark "DECA-DURABOLIN" in the U.S.). Contorting the meaning of Trademark Act Section 2(a) in an effort to shoehorn the facts of this case with a Section 2(a) cause of action is not the proper avenue by which to protect Opposer's alleged intellectual property rights.

As to the second prong of the test for false suggestion of a connection, because Opposer, as an institution or individual, has never been identified as "DURABOLIN" or "DECA-DURABOLIN", Applicant's mark does not point uniquely to Opposer's alleged "name or identity." *See University of Notre Dame du Lac*, 703 F.2d 1372.

As to the fourth prong of the test for false suggestion of a connection, Opposer's name or identity is not of sufficient fame or reputation that, when Applicant's "DECA-DURABOLIN" mark is used on its goods or services, potential consumers would presume a connection with the Opposer, Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.). As a result, the Board should grant Applicant's Motion for Summary Judgment and dismiss the Opposer's claim of false suggestion of a connection.

C. Applicant's Mark is Not Deceptive.

In order to prevail on a claim of deceptiveness of a non-geographic mark, the opposer must establish three critical elements, namely, (1) the term is misdescriptive of the character, quality, function, composition, or use of the goods, (2) prospective purchasers are likely to believe that the misdescription actually describes the goods, and (3) the misdescription is likely to affect the decision to purchase. *See* Lanham Act § 2(a); *see Hoover Co. v. Royal Applicant Mfg. Co.*, 238 F.3d 1357, 1361, 57 USPQ2d 1720, 1723 (Fed. Cir. 2001); *In re Budge Mfg. Co., Inc.*, 857 F.2d 773, 775, 8 USPQ2d 1259, 1260 (Fed. Cir. 1988). A cursory review of these three factors reveals that each factor requires the mark to be descriptive. Therefore, Applicant's non-geographic mark cannot be deceptive if it is not "misdescriptive of the character, quality, function, composition, or use of the goods." *See* Lanham Act § 2(a); *see, e.g., Hoover Co. v. Royal Applicant Mfg. Co.*, 238 F.3d 1357, 1361, 57 USPQ2d 1720, 1723 (Fed. Cir. 2001) (emphasis added).

Furthermore, the Board has previously held "that in order for a term to misdescribe goods or services, the term must be merely descriptive, rather than suggestive, of a significant aspect of the goods or services which the goods or services plausibly possess but in fact do not." [December 27, 2012 Board's Order] (quoting *In re Phillips-Van Heusen Corp.*, 63 USPQ2d 1047, 1051 (TTAB 2002)).

In the present case, the term "DECA-DURABOLIN" is not a descriptive term and in no way describes the goods "dietary and nutritional supplements." *See* [Wilson Decl. Ex. C] (showing that Merriam Webster's Dictionary has no definition for the terms "DURABOLIN" or "DECA-DURABOLIN"). The term "DECA-DURABOLIN" is actually a fanciful term when applied to "dietary and nutritional supplements." There is not a standard definition for the term "DECA-DURABOLIN", the term "DECA-DURABOLIN" does not contain a common descriptive phrase used in today's lexicon, and the term "DECA-DURABOLIN" does not identify any type of feature or ingredient of Applicant's goods. *See* TMEP §1209.01(b); *In re Disc Jockeys Inc.*, 23 USPQ2d 1715, 1716 (TTAB 1992) (citing *In re Uniroyal, Inc.*, 215 USPQ 716 (TTAB 1982)).

Moreover, on several occasions, the Opposer has confirmed that the term "DECA-DURABOLIN" is not a descriptive term. Perhaps most poignantly, the Opposer has already explicitly conceded that "'DECA-DURABOLIN' is *not* a descriptive term . . ." *See* [Opposer's Response to Applicant's Motion to Dismiss at pg. 9] (emphasis in original). In addition, despite alleging that Applicant's "DECA-DURABOLIN" is deceptive, the Opposer's first Notice of Opposition is wholly devoid of any allegation that the term "DECA-DURABOLIN" is descriptive. By failing to include an allegation of descriptiveness, the Opposer tacitly conceded that the term is not descriptive. The Opposer has also indicated that the mark "DECA-DURABOLIN" is currently registered in a number of foreign countries. *See* [Opposer's Amended Notice of Opposition at 3].

The fact that the term is capable of being registered in other countries clearly shows that the term "DECA-DURABOLIN" is not a descriptive term. Similarly, the fact that the Organon entity has twice registered the "DECA-DURABOLIN" trademark on the Principal Trademark Register of the USPTO clearly shows that it is a non-descriptive mark. *See* [Wilson Decl. Ex. A, B]. As a result, the Board should grant Applicant's Motion for Summary Judgment and dismiss the Opposer's claim of deceptiveness, because Applicant's "DECA-DURABOLIN" mark fails all three prongs of the test to determine whether a mark is deceptive.

D. Applicant's Mark is Not Deceptively Misdescriptive.

In order to prevail on a claim of deceptive misdescriptiveness of a non-geographic mark, the opposer must establish two crucial elements, namely, (1) the term misdescribes a characteristic, quality, function, composition, or use of the underlying goods or services, and (2) if so, that prospective purchasers are likely to believe that the misdescription actually describes the goods. *See* Lanham Act § 2(e)(1); *see In re Quady Winery, Inc.*, 221 USPQ 1213, 1214 (TTAB 1984). *See also Bureau Nat'l. Interprofessional Du Cognac v. Int'l Better Drinks Corp.*, 6 USPQ2d 1610, 1615 (TTAB 1988) (if the mark misdescribes the goods, and purchasers are likely to believe the misrepresentation, but the misrepresentation is not material to the purchasing decision, then the mark is deceptively misdescriptive); *In re Woodword & Lothrop Inc.*, 4 USPQ2d 1412, 1413 (TTAB 1987). A cursory review of these two factors reveals that both factors require the mark to be descriptive. Therefore, Applicant's non-geographic mark cannot be deceptive if it is not "misdescriptive of the character, quality, function, composition, or use of the goods." *See* Lanham Act § 2(e)(1); *see, e.g., In re Quady Winery, Inc.*, 221 USPQ 1213, 1214 (TTAB 1984) (emphasis added).

Furthermore, the Board has previously held "that in order for a term to misdescribe goods or services, the term must be merely descriptive, rather than suggestive, of a significant aspect of the goods or services which the goods or services plausibly possess but in fact do not." [December 27, 2012 Board's Order] (quoting *In re Phillips-Van Heusen Corp.*, 63 USPQ2d 1047, 1051 (TTAB 2002)).

In the present case, the term "DECA-DURABOLIN" is not a descriptive term and in no way describes the goods "dietary and nutritional supplements." The term "DECA-DURABOLIN" is actually a fanciful term when applied to "dietary and nutritional supplements." There is not a standard definition for the term "DECA-DURABOLIN", the term "DECA-DURABOLIN" does not contain a common descriptive phrase used in today's lexicon, and the term "DECA-DURABOLIN" does not identify any type of feature or ingredient of Applicant's goods. *See* TMEP §1209.01(b); *In re Disc Jockeys Inc.*, 23 USPQ2d 1715, 1716 (TTAB 1992) (citing *In re Uniroyal, Inc.*, 215 USPQ 716 (TTAB 1982)).

On several occasions, the Opposer has confirmed that the term "DECA-DURABOLIN" is not a descriptive term. Perhaps most poignantly, the Opposer has already explicitly conceded that "'DECA-DURABOLIN' is *not* a descriptive term . . ." *See* [Opposer's Response to Applicant's Motion to Dismiss at 9] (emphasis in original). In addition, despite alleging that Applicant's "DECA-DURABOLIN" is deceptive, the Opposer's first Notice of Opposition is wholly devoid of any allegation that the term "DECA-DURABOLIN" is descriptive. By failing to include an allegation of descriptiveness, the Opposer tacitly conceded that the term is not descriptive. The Opposer has also indicated that the mark "DECA-DURABOLIN" is currently registered in a number of foreign countries. *See* [Opposer's Amended Notice of Opposition at 3]. The fact that the term is capable of being registered in other countries clearly shows that the term "DECA-DURABOLIN"

is not a descriptive term. Similarly, the fact that the Organon entity has twice registered the "DECA-DURABOLIN" trademark on the Principal Trademark Register of the USPTO clearly shows that it is a non-descriptive mark. *See* [Wilson Decl. Ex. A, B]. As a result, the Board should grant Applicant's Motion for Summary Judgment and dismiss the Opposer's claim of deceptive misdescriptiveness, because Applicant's "DECA-DURABOLIN" mark fails both prongs of the test to determine whether a mark is deceptively misdescriptive.

IV. CONCLUSION

In summary, Applicant's "DECA-DURABOLIN" mark is not descriptive. Therefore, as a matter of law, Applicant's "DECA-DURABOLIN" mark cannot be a deceptive or deceptively misdescriptive mark. Additionally, Applicant's "DECA-DURABOLIN" mark is not the same as, or a close approximation of, the Opposer's previously used "name" or "identity", i.e. Merck Sharp & Dohme B.V. (as successor-in-interest to MSD OSS B.V.). Therefore, as a matter of law, Applicant's "DECA-DURABOLIN" mark cannot falsely suggest a connection with Opposer. For these reasons, Applicant respectfully requests that the Board Grant Applicant's Motion for Summary Judgment, that judgment is entered against Opposer, and that this opposition proceeding is dismissed with prejudice.

Respectfully submitted,

April 19, 2013
Date

/2259-36/

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Opposer,	§	
v.	§	Opposition No. 91205081
Dynamic Sports Nutrition, LLC,	§	
Applicant.	§	

DECLARATION OF KEVIN S. WILSON

1. "My name is Kevin S. Wilson. I am over the age of eighteen, have never been convicted of a felony, and am fully qualified to make this Declaration. I file this Declaration under 28 U.S.C. 1746.

2. I am an attorney with the office of Egbert Law Offices, PLLC, attorneys for Dynamic Sports Nutrition, LLC, in the above-entitled and numbered opposition proceeding. I have personal knowledge of the matters contained in this declaration, and if called upon to testify, I could and would testify competently thereto. I submit this affidavit in support of Applicant's Motion for Summary Judgment.

3. Attached hereto as **Exhibit A** is a true and correct copy of the TARR printout and Assignment pages from the United States Patent and Trademark Office's showing the relevant information and cancelled status of U.S. Reg. No. 2,932,737 for the mark "DECA-DURABOLIN" in the name of N.V. Organon Corporation, a predecessor to Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.) ("Opposer").

4. Attached hereto as **Exhibit B** is a true and correct copy of the TARR printout and Assignment pages from the United States Patent and Trademark Office's showing the relevant information and cancelled status of U.S. Reg. No. 641,324 for the mark "DECA-DURABOLIN" in the name of Organon, Inc., a predecessor to Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.) ("Opposer").

5. Attached hereto as **Exhibit C** is a true and correct copy of printouts from Merriam-Webster's Dictionary showing no definition for the terms "DURABOLIN" or "DECA-DURABOLIN". I personally printed out a copy of the pages on March 20, 2013.

6. Attached hereto as **Exhibit D** is a true and correct copy of printouts of the March 17, 2008 article titled "Important Information About Nandrolone in the U.S." from the blog titled "Surviving HIV". This article references the fact that nandrolone decanoate, the generic name for the product sold by Oreganon under the trademark "DECA-DURABOLIN", is no longer in production. Upon information and belief, Oreganon is a predecessor in interest to Opposer. I personally printed out a copy of the pages on March 20, 2013.

7. Attached hereto as **Exhibit E** is a true and correct copy of printouts of the August 10, 2010 Notice from Volume 75, No. 153 of the Federal Register by the Food and Drug Administration. This document states that Organon notified the FDA in a letter dated May 21, 2002 that it was discontinuing use of its product sold under the mark "DECA-DURABOLIN". I personally printed out a copy of the pages on March 20, 2013.

8. Attached hereto as **Exhibit F** is a true and correct copy of printouts from the website http://www.nelsonvergel.com/. This item references the fact that on March 20, 2007 Watson abandoned the drug nandrolone decanoate, which is sold under the brand name "DECA-DURABOLIN". I personally printed out a copy of the pages on March 20, 2013.

9. Attached hereto as **Exhibit G** is a true and correct copy of printouts of various internet cached articles from the Super Book Reading Blog. This document references the fact that "DECA-DURABOLIN" was introduced in the 1960's and began to take a back seat to "DURABOLIN". The article continues that "DURABOLIN" was not completely abandoned by Organon, as it is sold in select markets, most notably Portugal, India, Malaysia, Indonesia, Netherlands, Finland, and Taiwan. I personally printed out a copy of the pages on March 20, 2013.

9. Attached hereto as **Exhibit H** is a true and correct copy of printouts from the U.S. Food and Drug Administration's website regarding information found in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. This document serves as evidence that nandrolone decanoate, the generic name for the product sold by Oreganon USA Inc. under the trademark "DECA-DURABOLIN", was approved for production on June 12, 1986 but is currently listed as discontinued. Upon information and belief, Oreganon USA Inc. is a predecessor in interest to Opposer. I personally printed out a copy of the pages on April 15, 2013.

10. On March 26, 2013, counsel for both parties convened for the Discovery Conference. I personally attended the Discovery Conference. Then, prior to the filing of both Applicant's first Motion for Summary Judgment and the current Motion for Summary Judgment, on April 16, 2013 Applicant served Applicant's Initial Disclosures on counsel for the Opposer. Attached hereto as **Exhibit I** is a true and correct copy of Applicant's Initial Disclosures, as they were served on April 16, 2013.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing statements are true and correct."

Executed on the 18th day of April, 2013.

Kevin S. Wilson

Exhibit "A"

Generated on: This page was generated by TSDR on 2013-04-15 13:53:52 EDT

Mark: DECA-DURABOLIN

US Serial Number: 78230623 **Application Filing Date:** Mar. 27, 2003

US Registration Number: 2932737 **Registration Date:** Mar. 15, 2005

Register: Principal

Mark Type: Trademark

Status: Registration cancelled because registrant did not file an acceptable declaration under Section 8. To view all documents in this file, click on the Trademark Document Retrieval link at the top of this page.

Status Date: Oct. 21, 2011

Publication Date: Nov. 11, 2003

Date Cancelled: Oct. 21, 2011

Mark Information

Mark Literal Elements: DECA-DURABOLIN

Standard Character Claim: No

Mark Drawing Type: 1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)

Related Properties Information

Claimed Ownership of US Registrations: 0735928

Foreign Information

Foreign Registration Number: 19865 **Foreign Registration Date:** Mar. 29, 1971

Foreign Application/Registration Country: NETHERLANDS **Foreign Expiration Date:** Mar. 29, 2010

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Hormone Preparation, namely, steroids

International Class: 005 - Primary Class **U.S Class:** 006, 018, 044, 046, 051, 052

Class Status: SECTION 8 - CANCELLED

Basis: 44(e)

Basis Information (Case Level)

Filed Use: No	**Currently Use:** No	**Amended Use:** No
Filed ITU: Yes	**Currently ITU:** No	**Amended ITU:** No
Filed 44D: No	**Currently 44D:** No	**Amended 44D:** No
Filed 44E: Yes	**Currently 44E:** Yes	**Amended 44E:** No
Filed 66A: No	**Currently 66A:** No	
Filed No Basis: No	**Currently No Basis:** No	

Current Owner(s) Information

Owner Name: N.V. Organon

Owner Address: Klooserstraat6
Oss 5349 AB
NETHERLANDS

Legal Entity Type: CORPORATION

State or Country Where Organized: NETHERLANDS

Attorney/Correspondence Information

Attorney of Record

Attorney Name: James E. Rosini, Esq.

Docket Number: 13514/999

Attorney Primary Email Address: tmdocketny@kenyon.com

Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: JAMES E ROSINI ESQ
KENYON & KENYON
ONE BROADWAY
NEW YORK, NEW YORK 10004
UNITED STATES

Phone: 212-425-7200

Fax: 212-425-5288

Correspondent e-mail: tmdocketny@kenyon.com

Correspondent e-mail Authorized: Yes

Domestic Representative

Domestic Representative Name: James E. Rosini, Esq.

Phone: 2124257200

Fax: 2124255288

Domestic Representative e-mail: tmdocketny@kenyon.com

Domestic Representative e-mail Authorized: Yes

Prosecution History

Date	Description	Proceeding Number
Oct. 21, 2011	CANCELLED SEC. 8 (6-YR)	
Nov. 15, 2005	ATTORNEY REVOKED AND/OR APPOINTED	
Nov. 15, 2005	TEAS REVOKE/APPOINT ATTORNEY RECEIVED	
Mar. 15, 2005	REGISTERED-PRINCIPAL REGISTER	
Dec. 02, 2004	1(B) BASIS DELETED; PROCEED TO REGISTRATION	61756
Dec. 02, 2004	NOTICE OF ALLOWANCE CANCELLED	61756
Nov. 24, 2004	TEAS DELETE 1(B) BASIS RECEIVED	
Aug. 24, 2004	EXTENSION 1 GRANTED	
Aug. 03, 2004	EXTENSION 1 FILED	
Aug. 03, 2004	TEAS EXTENSION RECEIVED	
Jun. 15, 2004	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jun. 15, 2004	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Feb. 03, 2004	NOA MAILED - SOU REQUIRED FROM APPLICANT	
Nov. 11, 2003	PUBLISHED FOR OPPOSITION	
Oct. 22, 2003	NOTICE OF PUBLICATION	
Sep. 15, 2003	APPROVED FOR PUB - PRINCIPAL REGISTER	
Sep. 11, 2003	FAX RECEIVED	
Sep. 12, 2003	EXAMINER'S AMENDMENT MAILED	
Sep. 11, 2003	ASSIGNED TO EXAMINER	76624

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION

Date in Location: Mar. 15, 2005

United States Patent and Trademark Office

Assignments on the Web > Trademark Query

No assignment has been recorded at the USPTO

For Serial Number: 78230623

If you have any comments or questions concerning the data displayed, contact PRD / Assignments at 571-272-3350. v.2.3.2
Web interface last modified: July 10, 2012 v.2.3.2

Exhibit "B"

Generated on: This page was generated by TSDR on 2013-04-15 13:55:28 EDT

Mark: DECA-DURABOLIN

US Serial Number: 72136387 **Application Filing Date:** Jan. 23, 1962

US Registration Number: 735928 **Registration Date:** Aug. 14, 1962

Register: Principal

Mark Type: Trademark

Status: Registration cancelled because registrant did not file an acceptable declaration under Section 8. To view all documents in this file, click on the Trademark Document Retrieval link at the top of this page.

Status Date: May 17, 2003

Date Cancelled: May 17, 2003

Mark Information

Mark Literal Elements: DECA-DURABOLIN

Standard Character Claim: No

Mark Drawing Type: 1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)

Related Properties Information

Claimed Ownership of US Registrations: 0641324

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Hormone Preparation

International Class: 005 **U.S Class:** 018 - Primary Class

Class Status: SECTION 8 - CANCELLED

Basis: 1(a)

First Use: Jul. 07, 1960 **Use in Commerce:** Nov. 17, 1960

Basis Information (Case Level)

Filed Use: Yes	**Currently Use:** Yes	**Amended Use:** No
Filed ITU: No	**Currently ITU:** No	**Amended ITU:** No
Filed 44D: No	**Currently 44D:** No	**Amended 44D:** No
Filed 44E: No	**Currently 44E:** No	**Amended 44E:** No
Filed 66A: No	**Currently 66A:** No	
Filed No Basis: No	**Currently No Basis:** No	

Current Owner(s) Information

Owner Name: Organon Inc.

Owner Address: West Orange, NEW JERSEY
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW JERSEY

Attorney/Correspondence Information

Attorney of Record

Attorney Name: James E. Rosini, Esq.
Docket Number: 13514/999
Attorney Primary Email Address: tmdocketny@kenyon.com
Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: JAMES E ROSINI ESQ
KENYON & KENYON
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NEW YORK, NEW YORK 10004
UNITED STATES

Phone: 212-425-7200
Fax: 212-425-5288
Correspondent e-mail: tmdocketny@kenyon.com
Correspondent e-mail Authorized: Yes

Domestic Representative

Domestic Representative Name: James E. Rosini, Esq.
Phone: 2124257200
Fax: 2124255288
Domestic Representative e-mail: tmdocketny@kenyon.com
Domestic Representative e-mail Authorized: Yes

Prosecution History

Date	Description	Proceeding Number
Nov. 15, 2005	ATTORNEY REVOKED AND/OR APPOINTED	
Nov. 15, 2005	TEAS REVOKE/APPOINT ATTORNEY RECEIVED	
May 17, 2003	CANCELLED SEC. 8 (10-YR)/EXPIRED SECTION 9	
Oct. 25, 1984	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	
Aug. 14, 1982	REGISTERED AND RENEWED (FIRST RENEWAL - 20 YRS)	

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted
Affidavit of Incontestability: Section 15 - Accepted
Renewal Date: Aug. 14, 1982

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: Not Found
Date in Location: Not Found

United States Patent and Trademark Office

Assignments on the Web > Trademark Query

No assignment has been recorded at the USPTO

For Serial Number: 72136387

If you have any comments or questions concerning the data displayed, contact PRD / Assignments at 571-272-3350. v.2.3.2
Web interface last modified: July 10, 2012 v.2.3.2

Exhibit "C"

durabolin

The word you've entered isn't in the dictionary. Click on a spelling suggestion below or try again using the search bar above.

1. tourbillion
2. Durban
3. hydroplane
4. tarpaulin
5. durables
6. drop in
7. drop-in
8. trapline
9. Dearborn
10. dropping
11. turbulent

deca-durabolin

The word you've entered isn't in the dictionary. Click on a spelling suggestion below or try again using the search bar above.

Exhibit "D"

PoWeR

Roaming the USA and the globe for emerging and cutting edge HIV and health information usually not found in a doctor's office or in publications. A blog of Program for Wellness Restoration: www.powerusa.org

SEARCH THIS BLOG

Search

TRANSLATE

Select Language

Powered by Google Translate

FOLLOW BY EMAIL

Submit

CLICK HERE FOR MORE INFORMATION ABOUT OUR NON-PROFIT ORGANIZATION

PoWeR

FOLLOW US ON FACEBOOK

MONDAY, MARCH 17, 2008

IMPORTANT INFORMATION ABOUT NANDROLONE IN THE US

QUESTION FROM SOMEONE IN MY POZHEALTH AT YAHOOGROUPS.COM LIST:

"I interpret this that once the current supply of the components tomake nandrolone are depleted, there will be no more access tonandrolone here in the US. Am I right or just the number ofcompounding pharmacies may continue to dwindle due to DEA pressures?Thanks everyone,Tom A"

MY ANSWER:

Dear Tom

The ingredients to make nandrolone are not depleted. The decision from the manufacturer (Watson) to stop making nandrolone decanoate (an effective injectable medicine to treat unintentional weight loss and to increase muscle mass) was based on economics and political pressure.

Watson stopped making it because:

1- It is a generic CHEAP drug
2- They can sell expensive Oxandrin instead. Oxandrin is approved for unintentional weight loss but costs $1200 a month and can cause liver toxicity in some.
3- Nandrolone's indication is for anemia and no doctor uses it for that purpose, so they prescribe it legally off label.
4- Congress and the DEA are treating anabolics like the treat crack-cocaine and are closely watching every prescriber's and manufacturer's move. No HIV doc has ever got in trouble since many studies have shown nandrolone's benefit and can justify its medical use. However, inexperienced HIV doctors who have not been around long enough to know its history shy away from prescribing due to the bad publicity and misconceptions around these medicines.

Compounders picked it up and are making it cheap at $13 per 200 mg (1 cc). Watson's retail price was $48 per 200 mg (1 cc). Most people do ok with 1 cc a week along with daily testosterone gel. Most are able to gain 10 pounds of muscle slowly at this dose with the use of exercise and good nutrition. This amounts to a total cost of $52 a month, compared to $1200 a month for oral Oxandrin, another anabolic prescribed and approved for unintentional weight loss.

Nandrolone is the cheapest, cleanest, most effective medicine out there to increase muscle mass, strength and functional capacity. Like all medicines, it is only advisable to use it with doctor's supervision so that your hematocrit /hemoglobin, blood pressure, free testosterone/estradiol, and PSA are monitored. It has been studied in several HIV studies and it has been shown effective and low in side effects up to 600 mg a week. It has been studied in women with HIV also.

We are losing this drug in the US because patients who use it and love it are not empowered to fight back, even with Michael's, Al's and my help. More and more HIV doctors are getting afraid to prescribe it even after prescribing it without problems for 15 years. And most patients thing it is not available anymore, so they start oral Oxandrin at $1200 a month and experience liver problems.

I am glad someone in this list wrote a wonderful letter to congress, but it will take more from you guys than that. Calling your congress people, sending letters, and talking to your doctors are all a good start.

I will keep pushing. If the day comes when we have no nandrolone, I will opt for foreign travel. I am trying to get some small companies interested in it since there are enough data to go to the FDA with a new drug application (IND) for a HIV unintentional weight loss indication (I did not say "wasting" since most people do not lose 10% of their weight anymore unless they get PCP, excessive diarrhea, or other complications)

One important development:

Applied Pharmacy stopped all production due to DEA pressure. Some compounders are making doctors sign a waiver to say they will not prescribe nandrolone for non medical uses. Some doctors feel this represents extra liability. I am attaching the letter from Medaus so that you guys can see it.

So far, we are happy with these guys in Los Angeles. They ship anywhere after receiving a doctor's prescription

www.bbpharmacy.com
(562) 866-8363

FOR BACKGROUND INFORMATION (PRINT AND GIVE IT TO YOUR DOCTOR): http://savehivwastingmeds.blogspot.com/

This is the letter that Mark Mier from this list wrote recently. Please feel free to copy and paste text in it to write your own letter!

March 12, 2008

The Honorable Nancy Pelosi
Speaker of the United State House of Representatives
235 Cannon HOB
Washington, DC 20515

Subject: Representative Henry Waxman's Hearings on Steroids in Sports and the Impact on Treatments for HIV and other Medical Conditions

Dear Madam Speaker:

The hearings Representative Henry Waxman has been conducting with respect to steroids in sports have had an adverse impact upon treatment for a variety of medical condition for which anabolic steroids and human growth hormones are legitimately and legally used. Among those conditions is HIV, a matter of substantial concern to many in your own district.

The manner in which these hearings have been conducted has created a level of hysteria that has painted all anabolic supplements and medications as unsavory and illegitimate. Certainly illegal use of human growth hormones and steroids in both professional and youth sports is a concern that needs to be addressed. But Representative Waxman's hearings, as conducted, have highlighted only the negative aspects of such medicine and have not mentioned at all how they are properly and legitimately used and how controls on illegal use should be limited so as not to impact availability for proper usage. I am sure Representative Waxman appreciates the manner in which his name has been prominently highlighted in the press, but members in the HIV community have found him to have little interest in doing anything that will address our concerns in any concrete and demonstrable manner.

Anabolic steroids and recombinant human growth hormone are powerful prescriptive medicines that have been highly effective in treating cancer cachexia, MS, burns and HIV-related wasting and body changes. With respect to HIV, these treatments have been used successfully by thousands of sufferers in combating wasting, a condition which in the past was among the leading causes of death from AIDS. Since use of anabolic steroids and growth hormone to combat wasting began in the late 1980s, even before development of Highly Active Anti-Retroviral Therapy (HAART) used to combat HIV, thousands of lives have been saved.

The difficulty now is that anabolic steroids are becoming much less available legally because of Federal pressure upon producers. The anabolic steroid most successfully used over the years to combat wasting has been nandrolone decanoate. Up until recently, this product was produced by Watson Pharmaceuticals. In 2007, however, Watson stopped producing nandrolone. Instead, it is promoting Oxandrin, an oral steroid that is less effective and has more adverse side effects, but is also proprietary and therefore commands a higher price. Since then, anyone who needs to use nandrolone must go to compounding pharmacies, which will then produce the medicine on a custom order. At this time, the only anabolic steroids that may be used legally in the United States are Oxandrine and nandrolone. So the choice is Watson's expensive, less effective, propriety product or use of the compounding pharmacies.

This situation presents two major problems for patients who need anabolic therapies. The first is that a prescription filled by a compounding pharmacy is not covered by insurance or AIDS Drug Assistance Programs (ADAPs), so use of nandrolone is an out-of-pocket expense. Many patients suffering from HIV are in difficult economic circumstance. The added expense frequently puts the medicine out of reach.

The other problem is that compounding pharmacies are now under heavy scrutiny by the Drug Enforcement Agency to ensure that prescriptions are for legitimate medical needs. In theory, this would sound reasonable, but, in practice, the added delays, pressure and bureaucratic requirements have caused many compounding pharmacies to shy away from production of nandrolone. The most popular, Applied Pharmacy of Alabama, was providing the product reliably and at a reasonable price. However, the DEA insisted that the pharmacies verify the medical necessity of each prescription. That is not the role of a pharmacy. That is the role of the doctor writing the prescription. So the DEA regularly comes into the Applied Pharmaceuticals, gathers up all their records and keeps them for an unreasonable amount of time for review purposes. This amounts to blatant harassment solely to suppress production of a legitimate medication. For this reason, Applied

Pharmacy has announced that it will no longer provide nandrolone or other hormone-based products. Other compounding pharmacies have similarly so halted production, and this has caused an increase in prices among the remaining producers and confusion among HIV prescribers who wrongly assume that nandrolone is no longer available in the U.S.

The result, then, of Representative Waxman's hearings has been an attack on an important, powerful, beneficial and legal therapy solely because professional athletes use it improperly. Patients with legitimate medical needs should not be made to suffer because of the improper actions of a few. As for young athletes, for which use of anabolic steroids is a concern, I believe that virtually all of the drugs used by them are from black market sources. Legitimate pharmacies filling prescriptions for legitimate medical needs should not be harassed into curtailing production when they are not even the source of the problem.

What I would therefore request is that Representative Waxman hold hearings on the legitimate use of steroids and human growth hormones and the need to ensure that enforcement action against illegal use does not impede appropriate and necessary supplies. I would also ask that efforts be made to publicize these hearing to the same level as those held to highlight improper usage by athletes.

For more information on the impact current actions against anabolic steroids and human growth hormones have had on HIV treatment, I would recommend contacting Nelson Vergel and Michael Mooney, coauthors of Built to Survive, subtitled, "A Comprehensive Guide to the Medical Use of Anabolic Therapies, Nutrition and Exercise for HIV(+) Men and Woman." This book summarizes all the years of medical research using anabolics to improve health in people with HIV. Mr. Nelson and Mr. Mooney may be contacted through their web site at www.medibolics.com.

Sincerely,

Mark A. Meier

cc: Representative Henry Waxman 2204 Rayburn House Office Building Washington, DC 20515

Posted by Nelson Vergel at 4:52 PM Recommend this on Google

Labels: AIDS, anabolic steroids, compounding pharmacies, DEA, drug enforcement agency, Henry Waxman, HIV, HIV wasting, muscle, Nancy Pelosi, nandrolone

Links to this post

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LABELS

Exhibit "E"

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	400	20,000
107.50(c)(3)	3	10	30	300	9,000
Total					29,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3.—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
107.10(a) and 107.20	5	13	65	8	520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. All infant formula submissions to FDA may be provided in electronic format. The hours per response reporting estimates are based on FDA's experience with similar programs and information received from industry.

FDA estimates that it will receive 13 reports from 5 manufacturers annually under section 412(d) of the act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. FDA also estimates that it will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, FDA estimates that it will receive 2 reports from 3 manufacturers annually under §§ 107.50(b)(3) and (b)(4), for a total annual response of 6 reports. Each report is estimated to take 4 hours per response for a total of 24 hours. FDA also estimates that it will receive one notification under § 107.50(e)(2). The notification is expected to take four hours per response, for a total of four hours.

FDA estimates that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100. It is estimated that 3 firms will

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19640 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0218]

Determination That DECA-DURABOLIN (Nandrolone Decanoate) Injection, 200 Milligrams/Milliliter, 1 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 milligrams/milliliter (mg/mL), 1 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nandrolone decanoate, 200 mg/mL, 1 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug

417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug

(Organon), and was initially approved on October 5, 1962. Under the Drug Efficacy Study Implementation (DESI), FDA concluded that nandrolone decanoate was effective for the indications described in the **Federal Register** notice published on July 15, 1983 (DESI 7630, 48 FR 32394). DECA-DURABOLIN is an anabolic steroid indicated for the management of the anemia of renal insufficiency and has been shown to increase hemoglobin and red cell mass. Organon notified FDA in a letter dated May 21, 2002, that it was no longer marketing DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, and the drug product was moved to the "Discontinued Drug Product List" section of the Orange Book. PharmaForce, Inc., submitted a citizen petition dated May 7, 2009 (Docket No. FDA–2009–P–0218), under 21 CFR 10.30 requesting that the agency determine whether DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19698 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0391]

Determination That MOTRIN (Ibuprofen) Tablets and Four Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the five drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

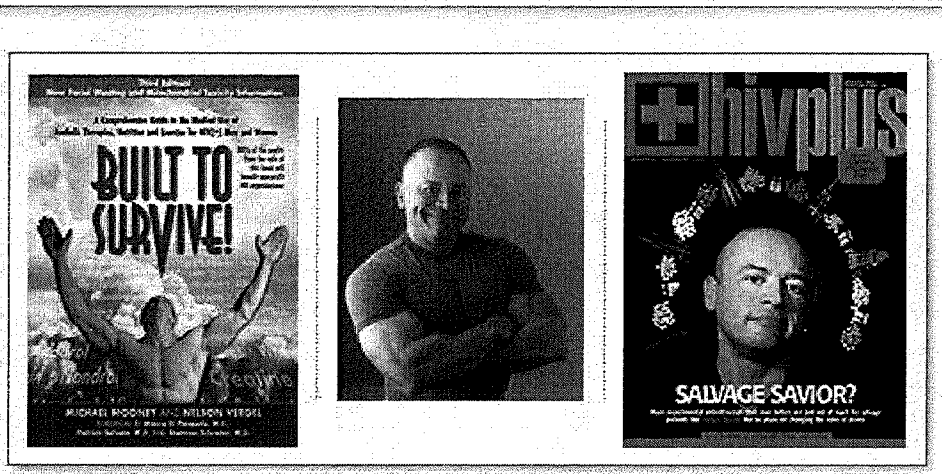
Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 18–354 for ORTHO–NOVUM 10/11–21 and 10/11–28 (ethinyl estradiol; norethindrone) Tablets in the **Federal Register** of February 11, 2009 (74 FR 6896).)

Exhibit "F"

NELSON VERGEL

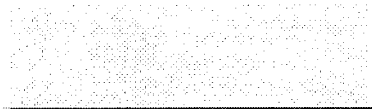
AUTHOR. ADVOCATE. LEADER. SURVIVOR.



- BOOKS
- PODCASTS
- RESOURCES
- BLOG
- ADVOCACY
- SPANISH
- VIDEOS
- CALENDAR

ADVOCACY.

- On March 20, 2007, Watson abandoned the cheapest and best AIDS Wasting Syndrome drug (nandrolone decanoate, brand name: Deca Durabolin) without any notice or successor to keep providing this medication to people with HIV. http://watsonboycott.blogspot.com/
- New Drugs Can Save Lives; AIDS Activists Urge Tibotec Pharmaceuticals Ltd To Be Compassionate Towards HIV Salvage Patients http://www.biospace.com/news_story.aspx?StoryID=11924&full=1
- Monoterapia virtual no, gracias (spanish) http://gtt-vih.org/node/605
- The AIDS Treatment Activists Coalition (ATAC), a group of US positive people who monitor drug access in the USA, are protesting at the steep price of the latest HIV drug to hit the market. http://uk.gay.com/article/3839



 Designed and Maintained by ABC Webservice

Exhibit "G"

William Llewellyn'S ANABOLICS, 9,th edt Dynabo/ (nandr%ne cypionate)

By admin | April 1, 2011 | Book Comments Off

William Llewellyn'S ANABOLICS, 9,th edt Dynabo/ (nandr%ne cypionate) Androgenic 37 Anabolic 125 Standard Testosterone Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Nandrolone cypionate is an injectable form of the anabolic steroid nandrolone. This ester provides a pattern of hormone release virtually identical to that of testosterone cypionate, with peak levels of drug being noted approximately 24-48 hours after administration, and a substantial hormone release sustained for about weeks. In this case the active hormone is nandrolone, which is a moderately strong anabolic steroid that carries mild estrogenic and androgenic properties. This product is essentially identical in overall effect to Deca-Ourabolin (nandrolone decanoate), producing measurable gains in strength and lean muscle mass, which tend to be accompanied byalowlevel ofside effects.Theonepointof difference is that nandrolone cypionate may appear to be a faster-acting compound to some users. OtherWise, there is no discernable difference between the two compounds, and nandrolone cypionate could replace nandrolone decanoate in virtually all cycles. History: Nandrolone cypionate was first developed during the 1960's. It was sold for a brief time as a human-use , pharmaceutical, under such brand names as Anabo, DepoNortestonate, Nortestrionate, and Sterocrinolo. Such preparations did not last, however, and in recent years the drug has been available only as a product of veterinary medicine. The most notable appearance has come from Jurox in Australia, which marketed a 50 mg/mL version of the drug called Dynabol 50. Jurox also included nandrolone cypionate as part of an anabolic steroid blend called

Nandrabolin. Both products, however, were discontinued in 2001, when Jurox scaled back its steroid line. This was likely done in response to media criticisms of heavy Australian veterinary exports to Mexico, which largely fuel the American black market. rhe discontinued Jurox products were quickly transferred o SYD Group in Australia, assuring they would not be 223 OH Nandrolone completely eliminated from commerce. They were subsequently reintroduced to market in 2002, under the names Anabolic DN and Anabolic NA, respectively.The new names made loose reference to the former Jurox trademarks, likely in an effort to retain some of the original market for the products. SYO Group had also introduced a high-dose version of Anabolic DN directly to the Mexican veterinary drug market, but the product has since been withdrawn. This time the product was discontinued following u.S. DEA charges against the firm, alleging that they were conspiring to illegally export Mexican steroids to the U.S. Today, the. Anabolic ON and Anabolic NA products remain available on the Australian veterinary drug market, although tight controls limit diversion for off-label use. How Supplied: Nandrolone cypionate is available on the Australian veterinary drug markets. It is supplied as 50 mg/mL of steroid dissolved in oil, in a 10 mL vial. Structural Characteristics: Nandrolone cypionate is a modified form of nandrolone where a carboxylic acid ester (cyclopentylpropionic acid) has been attached to the 17-beta hydroxyl group. Esterified steroids are less polar than free steroids, and are absorbed more slowly from the area of injection. Once in the bloodstream, the ester is removed to yield free (active) nandrolone. Esterified steroids are designed to prolong the window of therapeutic effect following administration, allowing for a less-frequent injection schedule compared to injections of free (unesterified) steroid. Nandrolone cypionate provides a sharp spike in nandrolone release 2448 hours following deep intramuscular injection, and sustains a substantial release of hormone for approximately 2 weeks. Side Effects (Estrogenic): Nandrolone has a low tendency for estrogen conversion, – William Llewellyn'S ANABOLICS, 9,th edt Dynabo/ (nandr%ne cypionate) Androgenic 37 Anabolic 125 Standard Testosterone Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Nandrolone cypionate is an injectable form of the anabolic steroid nandrolone. This ester provides a pattern of hormone release virtually identical to that of testosterone cypionate, with peak levels of drug being noted approximately 24-48 hours after administration, and a substantial hormone release sustained for about weeks. In this case the active hormone is nandrolone, which is a moderately strong anabolic steroid that carries mild estrogenic and androgenic properties. This product is essentially identical in overall effect to Deca-Ourabolin (nandrolone decanoate), producing measurable gains in strength and lean muscle mass, which tend to be accompanied byalowlevel ofside effects.Theonepointof difference is that nandrolone cypionate may appear to be a faster-acting compound to some users. OtherWise, there is no discernable difference between the two compounds, and nandrolone cypionate could replace nandrolone decanoate in virtually all cycles. History: Nandrolone cypionate was first developed during the 1960's. It was sold for a brief time as a human-use , pharmaceutical, under such brand names as Anabo, DepoNortestonate, Nortestrionate, and Sterocrinolo. Such preparations did not last, however, and in recent years the drug has been available only as a product of veterinary medicine. The most notable appearance has come from Jurox in Australia, which marketed a 50 mg/mL version of

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By admin | April 1, 2011 | Book Comments Off

William Llewellyn's ANABDLleS, 9th ed. day) and a natural cholesterol/antioxidant formula such as Lipid Stabil or a product with comparable ingredients is also recommended. Side Effects (Testosterone Suppression): All anabolic/androgenic steroids when taken in doses sufficient to promote muscle gain are expected to suppress endogenous testosterone production. Studies administering 100 mg injection of nandrolone phenylpropionate demonstrated a rapid suppression of serum testosterone following a single injection. Testosterone levels declined to approximately 300/0 of initial level by day 3 after drug administration, and stayed suppressed for approximately 13 days. Regular use is expected to significantly lengthen the endogenous hormone recovery window. It is believed that the progestational activity of nandrolone notably contributes to the suppression of testosterone synthesis during therapy, which can be marked in spite of a low tendency for estrogen

conversion.496 Without the intervention of testosterone-stimulating substances, testosterone levels should return to normal within 2-6 months of drug secession. Note that prolonged hypogonadotrophic hypogonadism can develop secondary to steroid abuse, necessitating medical intervention. The above side effects are not inclusive. For more detailed discussion ofpotential side effects, see the Steroid Side Effects section ofthis book. Administration (Men): For general anabolic effects, early prescribing guidelines recommend a dosage of 25-50 mg per week for 12 weeks. The usual dosage for physique-or performanceenhancing purposes is in the range of 200-400 mg per week, taken in cycles 8 to 12 weeks in length. This level is sufficient for most users to notice measurable gains in lean muscle mass and strength. Note that due to the fastacting nature of the phenylpropionate ester, the weekly dosage is usually subdivided into 2 separate applications spaced evenly apart. Administration (Women): For general anabolic effects, early prescribing guidelines recommend a dosage of 25-50 mg per week for 12 weeks. When used for physique-or performance-enhancing purposes, a dosage of 50 mg per week (given in a single weekly injection) is most common, taken for cycle lasting 4 to 6 weeks. Higher doses or longer durations of use are discouraged due to potential for androgenic side effects. Although only slightly androgenic, women are occasionally confronted with virilization symptoms when taking this compound. Should virilizing side effects become a concern, nandrolone phenylpropionate should be discontinued immediately to help prevent a permanent appearance. Availability: Although produced in a fair number of countries, Durabolin in not commonly found due to the high selling price and low strength of the Organon preparations. A single 50 mg ampule could cost as much as S15 when sold on the black market, which is usually the same price for 200 mg. Often the only strength available is the 25 mg version, which can be even less cost effective. The Organon preparations are not subject to high levels of counterfeiting, and can usually be trusted when located. Superanabolon from Spofa in the Czech Republic is also still in manufacture. It contains only 25 mg of steroid per 1 mL ampule, which makes it in relatively low demand among athletes. Still, it is a reputable product, with no major problems of fakes. Iran Hormone (Iran) makes a 25 mg/mL generic nandrolone phenylpropionate in 1 mL ampules. Counterfeits are not known to be a problem. –

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William Llewellyn's j'NABOLICS, 91h ed. Side Effects (Estrogenic):

By admin | March 31, 2011 | Book Comments Off

William Llewellyn's j'NABOLICS, 91h ed. Side Effects (Estrogenic): Nandrolone has a low tendency for estrogen conversion, estimated to be only about 200/0 of that seen with testosterone.488 This is because while the liver can convert nandrolone to estradiol, in other more active sites of steroid aromatization such as adipose tissue nandrolone is far less open to this process.489 Consequently, estrogenrelated side effects are a much lower concern with this drug than with testosterone. Elevated estrogen levels may still be noticed with higher dosing, however, and may cause side effects such as increased

water retention, body fat gain, and gynecomastia. An anti-estrogen such as clomiphene citrate or tamoxifen citrate may be necessary to prevent estrogenic side effects if they occur. One may alternately use an aromatase inhibitor like Arimidex (anastrozole), which more efficiently controls estrogen by preventing its synthesis. Aromatase inhibitors can be quite expensive in comparison to anti-estrogens, however, and may also have negative effects on blood lipids. It is of note that nandrolone has some activity as a progestin in the body.49o Although progesterone is a c-19 steroid, removal of this group as in 19-norprogesterone creates a hormone with greater binding affinity for its corresponding receptor. Sharing this trait, many 19-nor anabolic steroids are shown to have some affinity for the progesterone receptor as wel1.491 The side effects associated with progesterone are similar to those of estrogen, including negative feedback inhibition of testosterone production and enhanced rate offat storage. Progestins also augment the stimulatory effect of estrogens on mammary tissue growth. There appears to be a strong synergy between these two hormones here, such that gynecomastia might even occur with the help of progestins, without excessive estrogen levels. The use of an anti-estrogen, which inhibits the estrogenic component of this disorder, is often sufficient to mitigate gynecomastia caused by nandrolone. ilSide Effects (Androgenic): Although classified as an anabolic steroid, androgenic side effects are still possible with this substance, especially with higher doses. This may include bouts of oily skin, acne, and body/facial hair growth. Anabolic/androgenic steroids may also aggravate male pattern hair loss. Women are warned of the potential virilizing effects of 3nabolic/androgenic steroids. These may include a jeepening of the voice, menstrual irregularities, changes n skin texture, facial hair growth, and clitoral ~nlargement. Nandrolone is a steroid with relatively low lndrogenic activity relative to its tissue-building actions, naking the threshold for strong androgenic side effects omparably higher than with more androgenic agents such as testosterone, methandrostenolone, or fluoxymesterone.It is also important to point out that due to its mild androgenic nature and ability to suppress endogenous testosterone, nandrolone is prone to interfering with libido in males when used without another androgen. Note that in androgen-responsive target tissues such as the skin, scalp, and prostate, the relative androgenicity of nandrolone is reduced by its reduction to dihydronandrolone (DHN).492 493 The S-alpha. reductase enzyme is responsible for this metabolism of nandrolone. The concurrent use of a 5-alpha reductase inhibitor such as finasteride or dutasteride will interfere with sitespecific reduction of nandrolone action, considerably increasing the tendency of nandrolone to produce androgenic side effects. Reductase inhibitors should be avoided with nandrolone if low androgenicity is desired. Side Effects (Hepatotoxicity): Nandrolone is not c-17 alpha alkylated, and not known to have hepatotoxic effects. Liver toxicity is unlikely. Side Effects (Cardiovascular): Anabolic/androgenic steroids can have deleterious effects on serum cholesterol. This includes a tendency to reduce HDL (good) cholesterol values and increase LDL (bad) cholesterol values, which may shift the HDL to LDL balance in a direction that favors greater risk of arteriosclerosis. The relative impact of an anabolic/androgenic steroid on serum lipids is dependant on the dose, route of administration (oral vs. injectable), type of steroid (aromatizable or non-aromatizable), and level of resistance to hepatic metabolism. Studies administering 600 mg of nandrolone decanoate per week for 10 weeks demonstrated a 26% reduction in HDL cholesterol levels.494 This suppression is slightly greater than

that reported with an equal dose of testosterone enanthate, and is in agreement with earlier studies showing a slightly stronger negative impact on HDL/LDL ratio with nandrolone decanoate as compared to testosterone cypionate.495 Nandrolone should still have a significantly weaker impact on serum lipids than c-17 alpha alkylated agents. Anabolic/androgenic steroids may also adversely effect blood pressure and triglycerides, reduce endothelial relaxation, and support left ventricular hypertrophy, all potentially increasing the risk of cardiovascular disease and myocardial infarction. To help reduce cardiovascular strain it is advised to maintain an active cardiovascular exercise program and minimize the intake of saturated fats, cholesterol, and simple carbohydrates at all times during active AAS administration. Supplementing with fish oils (4 grams per 221 --

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William Llewellyn's ANABDLICS, HID eo. Durabolin (nandrolone phenylpropionate)

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William Llewellyn's ANABDLICS, HID eo. Durabolin (nandrolone phenylpropionate) Androgenic 37 Anabolic 125 Standard Testosterone Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Nandrolone phenylpropionate is an injectable form of the anabolic steroid nandrolone. The properties of this drug are strikingly similar to those of **Deca-Durabolin** , which uses the slower acting drug

nandrolone decanoate. The primary difference between these two preparations is the speed in which nandrolone is released into the blood. While nandrolone decanoate provides a release of nandrolone from the area of injection lasting approximately 3 weeks, nandrolone phenylpropionate is active for only about a week. In clinical situations, **DecaDurabolin** can thus be injected once every 2 or 3 weeks, while Durabolin is usually administered every several days to once weekly. Otherwise, the two drugs are virtually interchangeable. Like **Deca-Durabolin**, Durabolin is valued by athletes and bodybuilders for its abilities to promote strength and lean muscle mass gains without significant estrogenic or androgenic side effects. History: Nandrolone phenylpropionate was first described in 1957.487 It became a prescription medication shortly after, sold by the international pharmaceuticals giant Organon under the brand name Durabolin. When first introduced to the United States, indicated uses of nandrolone phenylpropionate included pre-and postoperative lean mass retention, osteoporosis, advanced breast cancer, weight loss due to convalescence or disease, geriatric states (general weakness and frailty), burns, severe trauma, ulcers, adjunct therapy with certain forms of anemia, and selective cases of growth and development retardation in children. During the 1970's, the FDA began revising the indicated uses of this drug, however, and they were soon significantly narrowed. Moving forward, the drug was mainly being indicated for the treatment of advanced metastatic breast cancer, and as adjunct therapy for the treatment of senile and post-menopausal osteoporosis. Durabolin was a key focus of Organon's marketing efforts 220 OH Nandrolone only for well less than a decade following its release. Once _ **Deca-Durabolin** was introduced during the 1960's, this shorter-acting counterpart, although still available, started to take a back seat. Durabolin was not completely **abandoned** by Organon, however, partly due to the fact that it was given a slightly different set of therapeutic uses in certain countries, and therefore continued to hold onto a niche market. As the size of the anabolic steroid market continued to grow throughout the 1970's and '80's, it was nandrolone decanoate that was attracting the most attention of other drug manufacturers. Numerous drug companies had produced their own versions of nandrolone phenylpropionate over the years, however,and the drug remains fairly available today. Organon continues to sell its original brand of Durabolin as well, but only in select markets, most notably Portugal, India, Malaysia, Indonesia, Netherlands, Finland, and Taiwan. How Supplied: Nandrolone phenylpropionate is available in select human drug markets. Composition and dosage may vary by country and manufacturer, but usually contain 25 mg/mL or 50 mg/mL of steroid dissolved in oil. Structural Characteristics: Nandrolone phenylpropionate is a modified form c nandrolone where a carboxylic acid ester (propionil phenyl este~) has been attached to the 17-beta hydrox) group. Esterified steroids are less polar than free steroidJ, and are absorbed more slowly from the area of injectio(Once in the bloodstream, the ester is removed to yield fre~ (active) nandrolone. Esterified steroi~s are designed. t1prolong the window of therapeutic effect followln~ administration, allowing for a less frequent injectiOjl schedule compared to injections of free (unesterified steroid. Nandrolone phenylpropionate provides a shar I spike in nandrolone release 24-48 hours following deeP I intramuscular injection, and declines to near baseline: levels within a week. –

William Llewellyn's ANABDLICS, HID eo. Durabolin (nandrolone phenylpropionate) Androgenic 37 Anabolic 125 Standard

Testosterone Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Nandrolone phenylpropionate is an injectable form of the anabolic steroid nandrolone. The properties of this drug are strikingly similar to those of **Deca-Durabolin** , which uses the slower acting drug nandrolone decanoate. The primary difference between these two preparations is the speed in which nandrolone is released into the blood. While nandrolone decanoate provides a release of nandrolone from the area of injection lasting approximately 3 weeks, nandrolone phenylpropionate is active for only about a week. In clinical situations, **DecaDurabolin** can thus be injected once every 2 or 3 weeks, while Durabolin is usually administered every several days to once weekly. Otherwise, the two drugs are virtually interchangeable. Like **Deca-Durabolin**, Durabolin is valued by athletes and bodybuilders for its abilities to promote strength and lean muscle mass gains without significant estrogenic or androgenic side effects. History: Nandrolone phenylpropionate was first described in 1957.487 It became a prescription medication shortly after, sold by the international pharmaceuticals giant Organon under the brand name Durabolin. When first introduced to the United States, indicated uses of nandrolone phenylpropionate included pre-and postoperative lean mass retention, osteoporosis, advanced breast cancer, weight loss due to convalescence or disease, geriatric states (general weakness and frailty), burns, severe trauma, ulcers, adjunct therapy with certain forms of anemia, and selective cases of growth and development retardation in children. During the 1970's, the FDA began revising the indicated uses of this drug, however, and they were soon significantly narrowed. Moving forward, the drug was mainly being indicated for the treatment of advanced metastatic breast cancer, and as adjunct therapy for the treatment of senile and post-menopausal osteoporosis. Durabolin was a key focus of Organon's marketing efforts 220 OH Nandrolone only for well less than a decade following its release. Once _ **Deca-Durabolin** was introduced during the 1960's, this shorter-acting counterpart, although still available, started to take a back seat. Durabolin was not completely **abandoned** by Organon, however, partly due to the fact that it was given a slightly different set of therapeutic uses in certain countries, and therefore continued to hold onto a niche market. As the size of the anabolic steroid market continued to grow throughout the 1970's and '80's, it was nandrolone decanoate that was attracting the most attention of other drug manufacturers. Numerous drug companies had produced their own versions of nandrolone phenylpropionate over the years, however,and the drug remains fairly available today. Organon continues to sell its original brand of Durabolin as well, but only in select markets, most notably Portugal, India, Malaysia, Indonesia, Netherlands, Finland, and Taiwan. How Supplied: Nandrolone phenylpropionate is available in select human drug markets. Composition and dosage may vary by country and manufacturer, but usually contain 25 mg/mL or 50 mg/mL of steroid dissolved in oil. Structural Characteristics: Nandrolone phenylpropionate is a modified form c nandrolone where a carboxylic acid ester (propionil phenyl este~) has been attached to the 17-beta hydrox) group. Esterified steroids are less polar than free steroidJ, and are absorbed more slowly from the area of injectio(Once in the bloodstream, the ester is removed to yield fre~ (active) nandrolone. Esterified steroi~s are designed. t1prolong the window of therapeutic effect followln~ administration, allowing for a less frequent injectiOjl schedule compared to injections of free (unesterified steroid.

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the bloodstream following oral administration. C17-alpha alkylated anabolic/androgenic steroids can be hepatotoxic. Prolonged or high exposure may result in liver damage. In rare instances life-threatening dysfunction may develop. It is advisable to visit a physician periodically during each cycle to monitor liver function and overall health. Intake of c17-alpha alkylated steroids is commonly limited to 6-8 weeks, in an effort to avoid escalating liver strain. Injectable forms of the drug may present slightly less strain on the liver by avoiding the first pass metabolism of oral dosing, although may still present substantial hepatotoxicity. Side Effects (Cardiovascular): Anabolic/androgenic steroids can have deleterious effects on serum cholesterol. This includes a tendency to reduce HDL (good) cholesterol values and increase LDL (bad) cholesterol values, which may shift the HDL to LDL balance in a direction that favors greater risk of arteriosclerosis. The relative impact of an anabolic/androgenic steroid on serum lipids is dependant on the dose, route of administration (oral vs. injectable), type of steroid (aromatizable or non-aromatizable), and level of resistance to hepatic metabolism. Methylandrostenediol has a strong effect on the hepatic management ofcholesterol due to its structural resistance to liver breakdown and (with the oral) route of administration. Anabolic/androgenic steroids may also adversely affect blood pressure and triglycerides, reduce endothelial relaxation, and support left ventricular hypertrophy, all potentially increasing the risk of cardiovascular disease and myocardial infarction. To help reduce cardiovascular strain it is advised to maintain an active cardiovascular exercise program and minimize the intake of saturated fats, cholesterol, and simple carbohydrates at all times during active AAS administration. Supplementing with fish oils (4 grams per day) and a natural cholesterol/antioxidant formula such as Lipid Stabil or a product with comparable ingredients is I also recommended. Side EffecWTestosterone Suppression): All anabolic/androgenic steroids when taken in doses sufficient to promote muscle gain are expected to suppress endogenous testosterone production. Without the intervention of testosterone-stimulating substances, testosterone levels should return to normal within 1-4 months of drug secession. Note that prolonged lypogonadotrophic hypogonadism can develop iecondary to steroid abuse, necessitating medical ntervention. ne above side effects are not inclusive. For more detailed william Llewellyn'S ANABOlleS, 9th ed. discussion ofpotential side effects, see the Steroid Side Effects section ofthis book. Administration (Men): Drive has not been approved for use in humans. Prescribing guidelines are unavailable. Typical dosing

schedule for physique-or performance-enhancing purposes would be in the range of 220 mg (4mL) to 440 mg (8mL) per week, a level that should provide quality lean mass gain without strong bloating or body fat retention. Due to the high injection volume and fastacting nature of methandriol dipropionate, the total weekly dosage is commonly divided into 2-3 smaller applications. Administration (Women): Drive has not been approved for use in humans. Prescribing guidelines are unavailable. Drugs containing methylandrostenediol are generally not recommended for women for physique-or performance-enhancing purposes due to its androgenic nature and tendency to produce virilizing side effects. Availability: Drive is rarely smuggled into the U.S. in noticeable quantity, but can be found on occasion. Its packaging is quite simple and easy to duplicate; most product bearing this name on the black market is actually counterfeit. 219 –_..._-~ , – the bloodstream following oral administration. C17-alpha alkylated anabolic/androgenic steroids can be hepatotoxic. Prolonged or high exposure may result in liver damage. In rare instances life-threatening dysfunction may develop. It is advisable to visit a physician periodically during each cycle to monitor liver function and overall health. Intake of c17-alpha alkylated steroids is commonly limited to 6-8 weeks, in an effort to avoid escalating liver strain. Injectable forms of the drug may present slightly less strain on the liver by avoiding the first pass metabolism of oral dosing, although may still present substantial hepatotoxicity. Side Effects (Cardiovascular): Anabolic/androgenic steroids can have deleterious effects on serum cholesterol. This includes a tendency to reduce HDL (good) cholesterol values and increase LDL (bad) cholesterol values, which may shift the HDL to LDL balance in a direction that favors greater risk of arteriosclerosis. The relative impact of an anabolic/androgenic steroid on serum lipids is dependant on the dose, route of administration (oral vs. injectable), type of steroid (aromatizable or non-aromatizable), and level of resistance to hepatic metabolism. Methylandrostenediol has a strong effect on the hepatic management ofcholesterol due to its structural resistance to liver breakdown and (with the oral) route of administration. Anabolic/androgenic steroids may also adversely affect blood pressure and triglycerides, reduce endothelial relaxation, and support left ventricular hypertrophy, all potentially increasing the risk of cardiovascular disease and myocardial infarction. To help reduce cardiovascular strain it is advised to maintain an active cardiovascular exercise program and minimize the intake of saturated fats, cholesterol, and simple carbohydrates at all times during active AAS administration. Supplementing with fish oils (4 grams per day) and a natural cholesterol/antioxidant formula such as Lipid Stabil or a product with comparable ingredients is I also recommended. Side EffecWTestosterone Suppression): All anabolic/androgenic steroids when taken in doses sufficient to promote muscle gain are expected to suppress endogenous testosterone production. Without the intervention of testosterone-stimulating substances, testosterone levels should return to normal within 1-4 months of drug secession. Note that prolonged lypogonadotrophic hypogonadism can develop iecondary to steroid abuse, necessitating medical ntervention. ne above side effects are not inclusive. For more detailed william Llewellyn'S ANABOlleS, 9th ed. discussion ofpotential side effects, see the Steroid Side Effects section ofthis book. Administration (Men): Drive has not been approved for use in humans. Prescribing guidelines are unavailable. Typical dosing schedule for physique-or performance-enhancing purposes would be in the range of 220 mg (4mL) to 440 mg (8mL) per

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William Llewellyn's ANABDLICS, 91n eo. Drive (boldenone/methylandrostenediol blend)

By admin | March 30, 2011 | Book Comments Off

William Llewellyn's ANABDLICS, 91n eo. Drive (boldenone/methylandrostenediol blend) Androgenic Anabolic Standard Chemical Names Estrogenic Activity Progestational Activity Description: Drive is an Australian injectable veterinary steroid preparation that contains a blend of methandriol dipropionate and boldenone undecylenate. The two steroids are present in a dose of 25 mg/mL and 30 mg/mL respectively, for a total steroid concentration of 55 mg/mL. Boldenone undecylenate is a highly common steroid most notably identified with the preparation Equipoise . Methandriol dipropionate, however, is very rarely seen on the U.S. black market. Its character is that of a moderately strong anabolic steroid, which is accompanied by a notable androgenic component. When combined with boldenone, the result is a moderately androgenic/anabolic blend inclined to produce notable muscle mass and strength gains, usually without excessive water retention. History: Drive is a product of RWR Veterinary Products (formerly a subsidiary of Nature Vet), sold only on the Australian veterinary drug market. It is designed for use in horses, typically as a general anabolic or health tonic drug for when an animal is weak from vigorous performance. It is supposed to aid the growth of muscle tissue, help avoid dehydration,and improve the digestion of dietary proteins. The dosage used for an adult 1,1 OOlb horse is 5 mL (110 mg) every two weeks. Australia is a country with a robust veterinary drug market, known to carry a variety of unusual steroids and odd multi-component steroid blends. Drive is perhaps the most well-known ofthese products. Being that it is neither the most concentrated preparation nor the most effective, however, much of its popularity is likely due to its well-coined trade name and early sales history. Drive remains on the Australina market today, although tight controls and its relatively low per-milliliter steroid concentration make diversion for athletic use much less common than it was many years ago. OH OH OH Boldenone Methandriol How Supplied: Drive is available on the Australian veterinary drug market. It contains 55 mg/mL of steroid in oil in a 10 mL vial.

Structural Characteristics: For a more comprehensive discussion of the individual steroids boldenone undecylenate and methandriol dipropionate, refer to their respective profiles. Side Effects (Estrogenic): Methylandrostendiol is not directly aromatized by th(body, although one of its known metabolites i: methyltestosterone, which can aromatize Methlyandrostenediol is also believed to have somE . inherent estrogenic activity.486 Combined with boldenone which also aromatizes, Drive is considered a moderatel) estrogenic steroid. Gynecomastia is possible durin treatment, but generally only when higher doses are used Water and fat retention can also become issues, agair, depending on dose. Sensitive individuals may need to adc an anti-estrogen such as Nolvadex to minimize relatec side effects. Side Effects (Androgenic): (Although classified as an anabolic steroid preparati~ androgenic side effects are still common with t~ substance. This may include bouts of oily skin, acne, arl body/facial hair growth. Anabolic/androgenic steroids ml also aggravate male pattern hair loss. Women are warn~1 of the potential virili~ing effects of an~bolic/androge.1 steroids. These may. Include a ~eep~nlng of the. VOI~, menstrual irregularities, changes In skin texture, faCial h~, growth, and clitoral enlargement. Side Effects (Hepatotoxicity): I I Methylandrostenediol is a c17-alpha alkylated compoun~ This alteration protects the drug from deactivation by th liver, allowing a very high percentage of the drug entry in~ I ! –

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William Llewellyn'S ANABDLICS, 9th ed. develop secondary to steroid abuse, necessitating medical intervention. The above side effects are not inclusive. For more detailed discussion ofpotential side effects, see the Steroid Side Effects section ofthis book. Administration (Men): To treat aplastic anemia, prescribing guidelines recommend a dosage of 50-200 mg per week. A 200 mg per week dose is recommended for anemia due to renal failure or cytotoxic therapy. When used for physique-or performance-enhancing purposes, a dose of 200-600 mg per week is most common, taken in cycles 8 to 12 weeks in length. This level is sufficient for most users to notice measurable gains in lean muscle mass and strength, which should be accompanied by a low level of estrogenic and androgenic activity. Due to the fast-acting nature of nandrolone phenylpropionate, the total weekly dosage is often divided into two separate applications, spaced several days apart. Note that as a nandrolone injectable, Dinandrol seems to fit well for both bulking and cutting purposes, and can reasonably replace **Deca-Durabolin** in most cycles. Administration (Women): To treat aplastic anemia, prescribing guidelines recommend a dosage of 50-200 mg per week. A 100 mg per week dose is recommended for anemia due to renal failure, and 200 mg per week for anemia caused by cytotoxic therapy. When used for physique-or performance-enhancing purposes, a dosage of 50 mg per week is most common, which is taken for 4 to 6 weeks. Although only slightly androgenic, women are

occasionally confronted with virilization symptoms when taking this compound, even when taking recommended therapeutic doses. Should virilizing side effects become a concern, the drug should be discontinued immediately to help prevent their permanent appearance. After a ~ufficient period of withdrawal, the shorter acting nandrolone Durabolin might be considered a safer (more controllable) option. This drug stays active for only ;everal days, greatly reducing the withdrawal time if ndicated. vailability:)inandrol is commonly found on the black market. Its lackaging is unique,and would seemingly be difficult and ostly to duplicate. To begin with, the product carries a ticker bearing the company logo, which, once removed) open the box, reads VOID.You also open the box to find le vials sitting in a clear-plastic tray that bears the firm's 3me (Xelox). It is not printed on the tray but molded rectly into the plastic, which would obviously be some task for an underground manufacturer to duplicate. Counterfeits of Dinandrol are currently not known to be a problem. 217

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It is of note that nandrolone has some activity as a progestin in the body.478 Although progesterone is a c-19 steroid, removal of this group as in 19-norprogesterone creates a hormone with greater binding affinity for its corresponding receptor. Sharing this trait, many 19-nor anabolic steroids are shown to have some affinity for the progesterone receptor as well.479 The side effects associated with progesterone are similar to those of estrogen, including negative feedback inhibition of testosterone production and enhanced rate of fat storage. Progestins also augment the stimulatory effect of estrogens on mammary tissue growth. There appears to be a strong synergy between these two hormones here, such that gynecomastia might even occur with the help of progestins, without excessive estrogen levels. The use of an anti-estrogen, which inhibits the estrogenic component of this disorder, is often sufficient to mitigate gynecomastia caused by nandrolone. Side Effects (Androgenic): Although classified as an anabolic steroid,androgenic side effects are still possible with this substance, especially with higher doses. This may include bouts of oily skin, acne, and body/facial hair growth. Anabolic/androgenic steroids may also aggravate male pattern hair loss. Women are warned of the potential virilizing effects of anabolic/androgenic steroids. These may include a deepening of the voice, menstrual irregularities, changes in skin texture, facial hair growth, and clitoral enlargement. Nandrolone is a steroid with relatively low androgenic activity relative to its tissue-building actions, making the threshold for strong androgenic side effects comparably higher than with more androgenic agents such as testosterone, methandrostenolone, or fluoxymesterone.It is also important to point out that due to its mild androgenic nature and ability to suppress endogenous testosterone, nandrolone is prone to interfering with libido in males when used without another androgen. Note that in androgen-responsive target tissues such as the skin, scalp, and prostate, the relative androgenicity of nandrolone is reduced by its reduction to dihydronandrolone (DHN).480 481 The S-alpha reductase enzyme is responsible for this metabolism of nandrolone. The concurrent use of a S-alpha reductase inhibitor such as finasteride or dutasteride will interfere with sitespecific reduction of nandrolone action, considerably increasing the tendency of nandrolone to produce androgenic side effects. Reductase inhibitors should be avoided with nandrolone if low androgenicity is desired. Side Effects (Hepatotoxi'city): Nandrolone is not c-17 alpha alkylated, and not known to have hepatotoxic effects. Liver toxicity is unlikely. Side Effects (Cardiovascular): Anabolic/androgenic steroids can have deleterious effeci on serum cholesterol. This includes a tendency to reducL HDL (good) cholesterol values and increase LDL (bad) cholesterol values, which may shift the HDL to LDL balance in a direction that favors greater risk of arteriosclerosis. The relative impact of an anabolic/androgenic steroid on serum lipids is dependant on the dose, route of administration

(oral vs. injectable), type of steroid (aromatizable or non-aromatizable), and level of resistance to hepatic metabolism. Studies administering 600 mg of nandrolone decanoate per week for 10 weeks demonstrated a 26% reduction in HDL cholesterol levels.482 This suppression is slightly greater than that reported with an equal dose of testosterone enanthate, and is in agreement with earlier studies showing a slightly stronger negative impact on HDL/LDL ratio with nandrolone decanoate as compared to testosterone cypionate.483 Nandrolone injectables, however, should still have a significantly weaker impact , on serum lipids than c-17 alpha alkylated agents. Anabolic/androgenic steroids may also adversely affect blood pressure and triglycerides, reduce endothelial relaxation, and support left ventricular hypertrophy, all potentially increasing the risk of cardiovascular disease and myocardial infarction. To help reduce cardiovascular strain it is advised to maintain an active cardiovascular exercise program and minimize the intake of saturated fats, cholesterol, and simple carbohydrates at all times during active AAS administration. Supplementing with fish oils (4 grams per day) and a natural cholesterol/antioxidant formula such as Lipid Stabil or a product with comparable ingredients if also recommended. Side Effects (Testosterone Suppression): All anabolic/androgenic steroids when taken in do/"" sufficient to promote muscle gain are expected suppress endogenous testosterone production. Stuc administering 100 mg per week of nandrolone decanq for 6 weeks have demonstrated an approximate 51 reduction in serum testosterone levels during therapYI a dosage of 300 mg per week, this reduction reac~1 700/0.484 It is believed that the progestational activit~I' nandrolone notably contributes to the suppression testosterone synthesis during therapy, which can I marked in spite of a low tendency for estrog conversion.485 Without the intervention of testostero~. stimulating substances, testosterone levels should retu to normal within 2-6 months of drug secession. Note t~ prolonged hypogonadotrophic hypogonadism ci 216 –
It is of note that nandrolone has some activity as a progestin in the body.478 Although progesterone is a c-19 steroid, removal of this group as in 19-norprogesterone creates a hormone with greater binding affinity for its corresponding receptor. Sharing this trait, many 19-nor anabolic steroids are shown to have some affinity for the progesterone receptor as well.479 The side effects associated with progesterone are similar to those of estrogen, including negative feedback inhibition of testosterone production and enhanced rate of fat storage. Progestins also augment the stimulatory effect of estrogens on mammary tissue growth. There appears to be a strong synergy between these two hormones here, such that gynecomastia might even occur with the help of progestins, without excessive estrogen levels. The use of an anti-estrogen, which inhibits the estrogenic component of this disorder, is often sufficient to mitigate gynecomastia caused by nandrolone. Side Effects (Androgenic): Although classified as an anabolic steroid,androgenic side effects are still possible with this substance, especially with higher doses. This may include bouts of oily skin, acne, and body/facial hair growth. Anabolic/androgenic steroids may also aggravate male pattern hair loss. Women are warned of the potential virilizing effects of anabolic/androgenic steroids. These may include a deepening of the voice, menstrual irregularities, changes in skin texture, facial hair growth, and clitoral enlargement. Nandrolone is a steroid with relatively low androgenic activity relative to its tissue-building actions, making the threshold for strong androgenic side effects comparably higher than with more

androgenic agents such as testosterone, methandrostenolone, or fluoxymesterone.It is also important to point out that due to its mild androgenic nature and ability to suppress endogenous testosterone, nandrolone is prone to interfering with libido in males when used without another androgen. Note that in androgen-responsive target tissues such as the skin, scalp, and prostate, the relative androgenicity of nandrolone is reduced by its reduction to dihydronandrolone (DHN).480 481 The S-alpha reductase enzyme is responsible for this metabolism of nandrolone. The concurrent use of a S-alpha reductase inhibitor such as finasteride or dutasteride will interfere with sitespecific reduction of nandrolone action, considerably increasing the tendency of nandrolone to produce androgenic side effects. Reductase inhibitors should be avoided with nandrolone if low androgenicity is desired. Side Effects (Hepatotoxi'city): Nandrolone is not c-17 alpha alkylated, and not known to have hepatotoxic effects. Liver toxicity is unlikely. Side Effects (Cardiovascular): Anabolic/androgenic steroids can have deleterious effeci on serum cholesterol. This includes a tendency to reducL HDL (good) cholesterol values and increase LDL (bad) cholesterol values, which may shift the HDL to LDL balance in a direction that favors greater risk of arteriosclerosis. The relative impact of an anabolic/androgenic steroid on serum lipids is dependant on the dose, route of administration (oral vs. injectable), type of steroid (aromatizable or non-aromatizable), and level of resistance to hepatic metabolism. Studies administering 600 mg of nandrolone decanoate per week for 10 weeks demonstrated a 26% reduction in HDL cholesterol levels.482 This suppression is slightly greater than that reported with an equal dose of testosterone enanthate, and is in agreement with earlier studies showing a slightly stronger negative impact on HDL/LDL ratio with nandrolone decanoate as compared to testosterone cypionate.483 Nandrolone injectables, however, should still have a significantly weaker impact , on serum lipids than c-17 alpha alkylated agents. Anabolic/androgenic steroids may also adversely affect blood pressure and triglycerides, reduce endothelial relaxation, and support left ventricular hypertrophy, all potentially increasing the risk of cardiovascular disease and myocardial infarction. To help reduce cardiovascular strain it is advised to maintain an active cardiovascular exercise program and minimize the intake of saturated fats, cholesterol, and simple carbohydrates at all times during active AAS administration. Supplementing with fish oils (4 grams per day) and a natural cholesterol/antioxidant formula such as Lipid Stabil or a product with comparable ingredients if also recommended. Side Effects (Testosterone Suppression): All anabolic/androgenic steroids when taken in do/"' sufficient to promote muscle gain are expected suppress endogenous testosterone production. Stuc administering 100 mg per week of nandrolone decanq for 6 weeks have demonstrated an approximate 51 reduction in serum testosterone levels during therapYI a dosage of 300 mg per week, this reduction reac~1 700/0.484 It is believed that the progestational activit~I' nandrolone notably contributes to the suppression testosterone synthesis during therapy, which can I marked in spite of a low tendency for estrog conversion.485 Without the intervention of testostero~. stimulating substances, testosterone levels should retu to normal within 2-6 months.of drug secession. Note t~ prolonged hypogonadotrophic hypogonadism ci 216

Dmandrolmandrownebkn~ Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low

By admin | March 28, 2011 | Book Comments Off

Dmandrolmandrownebkn~ Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Dinandrol is an injectable anabolic steroid preparation that contains a mixture of nandrolone phenylpropionate and nandrolone decanoate. The two steroids are present in a concentration of 40 mg/mL and 60 mg/mL, respectively. With a blend of fast-and slow-acting esters, this product was outwardly designed as a nandrolone equivalent of Sustanon or Testoviron. Given that nandrolone decanoate already provides its peak steroid release approximately 2448 hours post injection, however, as with Sustanon and Testoviron, a more even and sustained release of hormone is not actually achieved. Instead, Dinandrol can be looked at as a form of Deca-Durabolin that has a sharper shortterm spike of nandrolone following each injection, perhaps making it best to inject twice weekly as opposed to once. As with all nandrolone injectables, this preparation is favored by athletes and bodybuilders for its ability to promote moderate to strong gains in lean muscle mass, ' with minimal estrogenic or androgenic side effects. Historx; Dinandrol is a product of Xelox Pharma Co. in the I Philippines. Xelox is a licensed drug company, although lost of its steroid products are developed for export sales nly. The packaging for Dinandrol lists the indicated uses r the drug as being aplastic anemia, anemia caused by ytotoxic drugs, or anemia caused by chronic renal failure. wing to the fact that Deca-Durabolin is also approved for se in anemic patients in many markets, this drug could be iewed as a cheaper and often acceptable (although not eal) therapeutic alternative. Still, it is estimated that the ajority of steroid product that is traded on the ternational market is diverted to off-label use by athletes nd bodybuilders, usually in Europe and the United States, o it is uncertain how widely this drug is dispensed to egitimate patients. Dinandrol is occasionally smuggled nto the United States, though remains more widely istributed on less tightly controlled European markets. Androgenic Anabolic 'Standard 37 125 Testosterone OH Nandrolone How Supplied: Dinandrol is manufactured by Xelox Pharma in the Philippines. It contains 100 mg/mL of steroid in oil in a 2 mL vial. Structural Characteristics: Dinandrol contains a mixture of two nandrolone compounds, which where modified with the addition of carboxylic acid esters (propionic phenyl ester and decanoic acids) at the 17-beta hydroxyl group. Esterified steroids are less polar than free steroids, and are absorbed more slowly from the area of injection. Once in the bloodstream, the ester is removed to yield free (active) nandrolone. Esterified steroids are designed to prolong the window of therapeutic effect following administration, allowing for a less frequent injection schedule compared to injections of free (unesterified) steroid. Side Effects (Estrogenic): Nandrolone has a low tendency for estrogen conversion,

estimated to be only about 20% of that seen with testosterone.476 This is because while the liver can convert nandrolone to estradiol, in other more active sites of steroid aromatization such as adipose tissue nandrolone is far less open to this p rocess.477 Consequently, estrogen related side effects are a much lower concern with this drug than with testosterone. Elevated-estrogen levels may still be noticed with higher dosing, however, and may cause side effects such as increased water retention, body fat gain, and gynecomastia. An anti-estrogen such as clomiphene citrate or tamoxifen citrate may be necessary to prevent estrogenic side effects if they occur. One may alternately use an aromatase inhibitor like Arimidex (anastrozole), which more efficiently controls estrogen by preventing its synthesis. Aromatase inhibitors can be quite expensive in comparison to anti-estrogens, however, and may also have negative effects on blood lipids. 215 – Dmandrolmandrownebkn~ Chemical Names 19-norandrost-4-en-3-one-17beta-ol 17beta-hydroxy-estr-4-en-3-one Estrogenic Activity low Progestational Activity moderate Description: Dinandrol is an injectable anabolic steroid preparation that contains a mixture of nandrolone phenylpropionate and nandrolone decanoate. The two steroids are present in a concentration of 40 mg/mL and 60 mg/mL, respectively. With a blend of fast-and slow-acting esters, this product was outwardly designed as a nandrolone equivalent of Sustanon or Testoviron. Given that nandrolone decanoate already provides its peak steroid release approximately 2448 hours post injection, however, as with Sustanon and Testoviron, a more even and sustained release of hormone is not actually achieved. Instead, Dinandrol can be looked at as a form of Deca-Durabolin that has a sharper shortterm spike of nandrolone following each injection, perhaps making it best to inject twice weekly as opposed to once. As with all nandrolone injectables, this preparation is favored by athletes and bodybuilders for its ability to promote moderate to strong gains in lean muscle mass, ' with minimal estrogenic or androgenic side effects. Historx; Dinandrol is a product of Xelox Pharma Co. in the I Philippines. Xelox is a licensed drug company, although lost of its steroid products are developed for export sales nly. The packaging for Dinandrol lists the indicated uses r the drug as being aplastic anemia, anemia caused by ytotoxic drugs, or anemia caused by chronic renal failure. wing to the fact that Deca-Durabolin is also approved for se in anemic patients in many markets, this drug could be iewed as a cheaper and often acceptable (although not eal) therapeutic alternative. Still, it is estimated that the ajority of steroid product that is traded on the ternational market is diverted to off-label use by athletes nd bodybuilders, usually in Europe and the United States, o it is uncertain how widely this drug is dispensed to egitimate patients. Dinandrol is occasionally smuggled nto the United States, though remains more widely istributed on less tightly controlled European markets. Androgenic Anabolic 'Standard 37 125 Testosterone OH Nandrolone How Supplied: Dinandrol is manufactured by Xelox Pharma in the Philippines. It contains 100 mg/mL of steroid in oil in a 2 mL vial. Structural Characteristics: Dinandrol contains a mixture of two nandrolone compounds, which where modified with the addition of carboxylic acid esters (propionic phenyl ester and decanoic acids) at the 17-beta hydroxyl group. Esterified steroids are less polar than free steroids, and are absorbed more slowly from the area of injection. Once in the bloodstream, the ester is removed to yield free (active) nandrolone. Esterified steroids are designed to prolong the window of therapeutic effect following administration, allowing for a less frequent injection schedule compared to

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nlillilill LIIIWIiIlJII a nllnDULI..., 0111 uu. hepatotoxicity. Those

By admin | March 28, 2011 | Book Comments Off

nlillilill LIIIWIiIlJII a nllnDULI..., 0111 uu. hepatotoxicity. Those absolutely insisting on its use need to take its level of liver toxicity very seriously. At the very least, routine blood tests should be conducted to ensure the agent is not imparting damage. Drug duration is also usually very limited, typically to 4 weeks of use or less. The relative potency of dimethyltrienolone is extremely high, requiring doses as little as .25 (1/4) milligram per day for a pronounced anabolic effect (.25 to 1mg likely being the chosen range).It needs to be emphasized again that there are many other steroids out there worth using before this one, which are not going to be as dangerous. No compound, no matter how potent, is magic, and dimethyltrienolone is one of those steroids that should probably just be left alone. Administration (Women): Dimethyltrienolone was never approved for use in humans. Prescribing guidelines are unavailable.This agent is not recommended for women for physique-or performance-enhancing purposes due to its extremely strong toxicity and tendency to produce virilizing side effects. Availability: Dimethyltrienolone is not produced as a prescription steroid product in any part of the world. This agent is available as a black market designer compound, however. Those contemplating the use of underground forms of dimethyltrienolone should consider that such agents are being released for human use without any government approval or consideration to its safety. –

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« ‹ 11 12 13 14 15 › »

Exhibit "H"

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

FDA Home[3] Drug Databases[4] Orange Book[5]

Search results from the "OB_Disc" table for query on "013132."

Active Ingredient:	NANDROLONE DECANOATE
Dosage Form;Route:	INJECTABLE; INJECTION
Proprietary Name:	DECA-DURABOLIN
Applicant:	ORGANON USA INC
Strength:	50MG/ML
Application Number:	N013132
Product Number:	001
Approval Date:	Jun 12, 1986
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View
Active Ingredient:	NANDROLONE DECANOATE
Dosage Form;Route:	INJECTABLE; INJECTION
Proprietary Name:	DECA-DURABOLIN
Applicant:	ORGANON USA INC
Strength:	100MG/ML
Application Number:	N013132
Product Number:	002
Approval Date:	Jun 12, 1986
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View
Active Ingredient:	NANDROLONE DECANOATE
Dosage Form;Route:	INJECTABLE; INJECTION
Proprietary Name:	DECA-DURABOLIN
Applicant:	ORGANON USA INC
Strength:	200MG/ML
Application Number:	N013132
Product Number:	003
Approval Date:	Jun 12, 1986
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page [6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through March, 2013
Patent and Generic Drug Product Data Last Updated: April 15, 2013

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2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

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- Health Professionals

U.S.Department of **Health & Human Services**

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Exhibit "I"

EGBERT LAW OFFICES, PLLC
GREAT SOUTHWEST BUILDING
1314 TEXAS, 21st FLOOR
HOUSTON, TEXAS 77002

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FACSIMILE (713) 223-4873
mail@egbertlawoffices.com

PATENT, TRADEMARK,
COPYRIGHT &
TECHNOLOGY-RELATED MATTERS

April 16, 2013

Marie Lavalleye
Hope Hamilton
Bingham Leverich
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004

VIA REGULAR MAIL

Re: Our File: 2259-36
For: Trademark "DECA-DURABOLIN"
Opposition No. 91205081
MSD Oss B.V. v. Dynamic Sports Nutrition, LLC

Dear Ms. Lavalleye:

Please find the following document, which has been sent via first class mail on this day to be served in the above-mentioned opposition proceeding:

- Applicant's Initial Disclosures

If you have any other questions or concerns regarding this matter, please feel free to contact us at any time.

Sincerely,

Kevin S. Wilson

Enclosure
KSW:mfs

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Trademark Application No. 85/340,058
Published in the Official Gazette on January 10, 2012

Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.),	§	
Opposer,	§	
v.	§	Opposition No. 91205081
Dynamic Sports Nutrition, LLC,	§	
Applicant.	§	

APPLICANT'S INITIAL DISCLOSURES

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure and Rule 2.120 of the Trademark Rules of Practice, Dynamic Sports Nutrition, LLC (hereinafter "Applicant"), a limited liability company of Texas, hereby makes the following initial disclosures.

These disclosures are based on information reasonably available to Applicant as of this date and represent a good-faith effort to identify information Applicant reasonably believes is discoverable and relevant to the factual dispute alleged with the particularity required by Rule 26(a)(1) of the Federal Rules of Civil Procedure. Continuing investigation and discovery may alter these disclosures. Therefore, in making these disclosures, Applicant does not represent that it is identifying every document, tangible thing or witness possibly relevant to this opposition proceeding. Nor does the Applicant waive any right to object to the production of any document or tangible thing disclosed herein on the basis of any privilege, work-product doctrine, irrelevance, undue burden or any other objection.

A. Persons Likely to Have Discoverable Information

In addition to the persons named in Merck Sharp & Dohme B.V.'s (as successor in interest to MSD OSS B.V.) (hereinafter "Opposer") Initial Disclosures or identified in any answer to interrogatory in this matter, Applicant believes the following persons are likely to have discoverable information:

Name and Address	Subjects
Mr. Brian Clapp President Dynamic Sports Nutrition, LLC 1330 Post Oak Blvd., Ste. 2900 Houston, Texas 77056	Applicant's knowledge of prosecution of its mark; Applicant's knowledge of this opposition proceeding; Applicant's intended use of Applicant's mark in the future, both foreign and domestic; Applicant's decision to choose Applicant's mark; the goods to be promoted through the use of Applicant's mark; Applicant's first knowledge of Opposer's alleged mark at issue in this proceeding; Applicant's decision to file the Applicant's application; the geographical scope of Applicant's intended use of Applicant's mark; Applicant's advertisements, foreign and/or domestic, showing any intentions of Applicant to advertise under Applicant's mark in the future; Applicant's intended expenditures in connection with promotions of goods and services using Applicant's mark or any intended promotions thereof; description of products to be sold under Applicant's mark; channels of trade for products to be sold under Applicant's mark; the manufacture or production of products to be sold under Applicant's mark.
Mr. John S. Egbert, Esq. 1314 Texas, 21st Floor Houston, TX 77002	Matters related to the prosecution of the Applicant's application; matters related to the current Opposition proceeding.

Applicant expressly reserves the right to identify and/or rely on all other persons identified in Opposer's Initial Disclosures or identified in an answer to any interrogatory in this matter. In addition, Applicant reserves the right to identify additional persons if, during the course of discovery

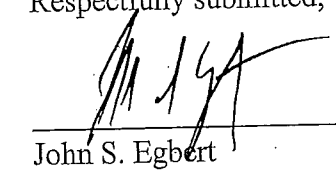
and investigation relating to this case, Applicant learns that such additional persons are relevant to its defenses.

B. Relevant Documents

In addition to the categories to be set forth in Applicant's requests for production of documents and things, Applicant may use the following categories of documents that are in its custody, possession or control to support its defenses in this matter, unless used solely for impeachment:

1. Documents related to Applicant's intended use of Applicant's "DECA-DURABOLIN" mark.
2. Applicant's Serial No. 85/340,058, and documents related thereto.
3. Documents related to the channels of trade and classes of consumers for goods intended to be sold under Applicant's mark.
4. Documents evidencing Applicant's intent to use Applicant's mark.
5. Documents related to Opposer's abandonment of its "DURABOLIN" and "DECA-DURABOLIN" marks.

Respectfully submitted,



April 16, 2013
Date

John S. Egbert
Reg. No. 30,627
Kevin S. Wilson
Michael F. Swartz

Egbert Law Offices, PLLC
1314 Texas, 21st Floor
Houston, Texas 77002
(713)224-8080
(713)223-4873 (Fax)

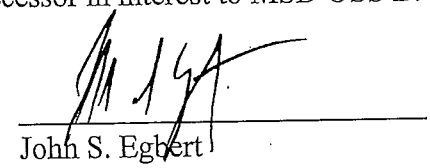
ATTORNEY FOR APPLICANT
Dynamic Sports Nutrition, LLC

CERTIFICATE OF SERVICE

I hereby certify that Applicant's Initial Disclosures is being sent by first class mail on April 16, 2013, to the attorney of record for Opposer at the following address:

Marie Lavalleye
Hope Hamilton
Bingham Leverich
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004

ATTORNEY FOR OPPOSER
Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.)



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Dynamic Sports Nutrition, LLC

JSE:mfs
Our File: 2259-36