

ESTTA Tracking number: **ESTTA621104**

Filing date: **08/13/2014**

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

| | |
|------------------------|---|
| Proceeding | 91205081 |
| Party | Defendant Dynamic Sports Nutrition, LLC |
| Correspondence Address | JOHN S EGBERT EGBERT LAW OFFICES PLLC 1314 TEXAS AVENUE, 21ST FLOOR HOUSTON, TX 77002-1897 UNITED STATES mail@egbertlawoffices.com |
| Submission | Opposition/Response to Motion |
| Filer's Name | John S. Egbert |
| Filer's e-mail | mail@egbertlawoffices.com |
| Signature | /2259-36_78/ |
| Date | 08/13/2014 |
| Attachments | 2259-36 Response to Opposer's Motion to Substitute.pdf(1380042 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, | § | |
| | § | |
| v. | § | Opposition No. 91205081 |
| | § | |
| Dynamic Sports Nutrition, LLC, | § | |
| | § | |
| Applicant. | § | |

In the Matter of Trademark Application No. 85/628,632
Published in the Official Gazette on January 29, 2013

| | | |
|--------------------------------|---|-------------------------|
| Merck Sharp & Dohme B.V., | § | |
| | § | |
| Opposer, | § | |
| | § | |
| v. | § | Opposition No. 91210254 |
| | § | |
| Dynamic Sports Nutrition, LLC, | § | |
| | § | |
| Applicant. | § | |

**APPLICANT'S RESPONSE TO OPPOSER'S MOTION FOR SUBSTITUTION OF
ASPEN GLOBAL INCORPORATED AS OPPOSER OF RECORD IN OPP. NO. 9120581
(PARENT)**

Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.) ("Opposer"), has moved under TBMP § 512.01 for substitution of Aspen Global Incorporated ("Aspen") to be the opposer in the parent opposition. Dynamic Sports Nutrition, LLC ("Applicant") hereby opposes the Opposer's Motion for Substitution. In support of its Response and Opposition, Applicant states as follows:

ARGUMENT

Substitution of Aspen as the opposer is not proper, because it is untimely for Aspen, a company that existed during the opposition period, to oppose Applicant's "DECA-DURABOLIN" trademark application. Aspen did not timely oppose Applicant's trademark application at issue. Since Aspen could have opposed Applicant's trademark application if it felt it had a cause of action, an opposition should have been filed within the opposition period. It is well understood that "a party may oppose within thirty days after publication or within an extension of time." *See* Trademark Rule 2.101(c). Aspen cannot meet either of these two requirements. As explained by case law, "once a timely notice of opposition has been filed, and the time for opposing has expired, the right to pursue the filed case is a right individual to the timely filer." *See SDT Inc. v. Patterson Dental Co.*, 30 USPQ2d 1707 (TTAB 1994). Contrary to the claims in Opposer's Motion, Aspen is not a new owner or transferee of rights to the original Opposer's mark, because the Opposer did not plead a mark in this Opposition. Finally, Aspen is a completely new entity that has not paid the opposition filing fee. As such, Aspen cannot be substituted as the Opposer in this opposition.

Substitution of Aspen as the opposer is not proper, because the Opposer has not plead an ownership interest in the mark "DECA-DURABOLIN" in the United States. As elucidated by the Opposer's Motion for Substitution, substitution is appropriate when "there has been an assignment of a mark that is the subject of, or relied upon in, an inter partes proceeding before the Board." T.B.M.P. §512.01 (emphasis added). In this case, the Opposer has not purported to have any ownership interest in the mark "DECA-DURABOLIN" in the United States. In fact, the Opposer has already admitted that it does not use the mark "DECA-DURABOLIN" in the U.S. *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"). Since the Opposer does not have an ownership interest in the "DECA-DURABOLIN" mark in the United States, it would be impossible for the Opposer to assign a mark that is the subject of, or relied upon, in the current proceeding, because a mark is not being relied on in the proceeding. Moreover, a property right does not exist at all due to abandonment in the United States.

The Opposer has not provided any evidence whatsoever that an assignment of any alleged "DECA-DURABOLIN" mark, either common law or trademark registration, has taken place. However, even accepting the entire Ahmed Declaration as true, and thereby accepting that "Aspen agreed to purchase and Organon agreed to cause Merck to sell to Aspen, all of Merck's rights, title, and interest worldwide in and to the 'DECA-DURABOLIN' mark," the crucial fact remains that Organon and Merck's worldwide rights, title, and interest in and to the "DECA-DURABOLIN" mark that were transferred do not include the United States. *See* Ahmed Decl. at ¶ 5 (indicating that worldwide rights in the "DECA-DURABOLIN" mark have been transferred, but failing to indicate that there are any rights to the "DECA-DURABOLIN" mark in the United States). Furthermore, Mr. Ahmed's Declaration is wholly devoid of any reference to an ownership claim by Organon, Merck, or any other entity to the "DECA-DURABOLIN" mark in the United States. Once again, the failure to include reference to an ownership claim is because there is no property interest in such a term.

The reality remains that the Opposer unequivocally abandoned its "DECA-DURABOLIN" trademark long ago. *See* [Opposer's Amended Notice of Opposition, pg. 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* [Exhibit A and B,

Title and Status of cancelled "DECA-DURABOLIN" trademark registrations] (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); *see also* [Exhibit C, August 10, 2010 Notice from Vol. 75, No. 153 of Federal Register by FDA] (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.). Furthermore, the Opposer never plead an ownership interest in the mark "DECA-DURABOLIN" in the United States. *See* [Opposer's Amended Notice of Opposition] (illuminating that the Opposer's Notice of Opposition is wholly devoid of any claim of an ownership interest in the "DECA-DURABOLIN" mark in the United States). Without an ownership interest in the "DECA-DURABOLIN" mark in the United States, there is no transfer of interest in any property right in the United States that would warrant a substitution of the Opposer.

Applicant notes that a Opposer's Motion to Substitute is the improper vehicle by which Opposer would hope to make Aspen as the opposer in the Opposition, and Opposer's Motion is procedurally deficient. The Board's rules explain that:

If a mark pleaded by a plaintiff is assigned and a copy of the assignment is filed with the Board, the assignee ordinarily will be substituted for the originally named party if the assignment occurred prior to the commencement of the proceeding, if the discovery and testimony periods have closed, if the assignor is no longer in existence, or if the defendant raises no objection to substitution. Otherwise, the assignee will be joined, rather than substituted, to facilitate the taking of discovery and the introduction of evidence.

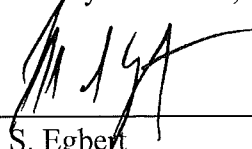
See TBMP § 512.01 (emphasis added). In this case, the Opposer has not pleaded a mark. Nonetheless, if the Opposer had pleaded a mark and it was assigned, a copy of the assignment should have been filed with the Board. Even assuming that the Opposer had pleaded a mark and a purported

assignment was filed with the Board, the purported assignment has certainly not occurred prior to the Opposition being filed. Furthermore, in this case, the discovery period is still open, the assignor is still in existence, and the Applicant has objected to the Opposer's Motion. Therefore, under the completely hypothetical circumstances laid out above, since there is not a pleaded mark, a motion to join, rather than substitute, would be appropriate.

CONCLUSION

Therefore, Applicant respectfully requests that Opposer's Motion for Substitution of Aspen as Opposer of record in Opposition No. 9120581 be denied. If Merck Sharp & Dohme B.V. (as successor in interest to MSD OSS B.V.) is no longer interested in pursuing its Opposition against the "DECA-DURABOLIN" trademark application, the proper action would be for Merck to withdraw the Opposition. It is improper to attempt to transfer the Opposition to another party in a manner that vitiates the Lanham Act. If this type of action was allowed by the Board in this and similar circumstances, any party could shop around for industry competitors to take over a case that the entity has lost interest in for some reason. The Lanham Act does not allow for such circumstances, and Applicant respectfully requests that the Opposer's Motion to Substitute be denied.

Respectfully submitted,



August 13, 2014
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)

ATTORNEYS FOR APPLICANT
Dynamic Sports Nutrition, LLC

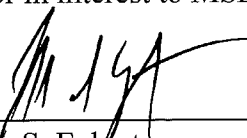
CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document is being sent by first class mail on August 13, 2014, 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

ATTORNEYS FOR OPPOSER

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



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)

ATTORNEYS FOR APPLICANT
Dynamic Sports Nutrition, LLC

JSE:mfs
Our File: 2259-36/78

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: Kloosterstraat6
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: tmocketny@kenyon.com Attorney Email Address: Yes
Authorized:

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: tmocketny@kenyon.com Correspondent e-mail Address: Yes
Authorized:

Domestic Representative

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

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

[Home](#) | [Site Index](#) | [Search](#) | [Guides](#) | [Contacts](#) | [eBusiness](#) | [eBiz alerts](#) | [News](#) | [Help](#)



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. v2.3.2
Web interface last modified: July 10, 2012 v2.3.2

[.HOME](#) | [INDEX](#) | [SEARCH](#) | [eBUSINESS](#) | [CONTACT US](#) | [PRIVACY STATEMENT](#)

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 0641324
Registrations:

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: tmocketny@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: tmocketny@kenyon.com

Correspondent e-mail Authorized: Yes

Domestic Representative

Domestic Representative Name: James E. Rosini, Esq.

Phone: 2124257200

Fax: 2124255288

Domestic Representative e-mail: tmocketny@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

[Home](#) | [Site Index](#) | [Search](#) | [Guides](#) | [Contacts](#) | [eBusiness](#) | [eBiz alerts](#) | [News](#) | [Help](#)



[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. v2.3.2
Web interface last modified: July 10, 2012 v2.3.2

[.HOME](#) | [INDEX](#) | [SEARCH](#) | [eBUSINESS](#) | [CONTACT US](#) | [PRIVACY STATEMENT](#)

Exhibit "C"

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 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 BURDEN¹

| 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

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:

Nancy A. Mynors, 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

