West Higgins Road, Suite 150, Hoffman Estates, IL 60195, Officers: Janet Fiore, Secretary (Qualifying Individual), David Kratt, President.

Elite Transportation Services, LLC dba Elite Logistics Worldwide, 6600 NE 78th Ct., Portland, OR 97218, Officer: David DeBoer, Vice President (Qualifying Individual).

Procargo USA LLC, 1360 NW. 78 Ave., Doral, FL 33126, Marcelo A. Leston, Manager (Qualifying Individual).

Temma Freight Logistics, Inc., 8372 NW. 68th Ter., Miami, FL 33166, Officers: Aymara Sucre, COO (Qualifying Individual), Gregorio Farfan, President.

Dakini International Logistics Inc., 36707 212th Way SE., Auburn, WA 98092, Officers: Terri L. Danz, Director (Qualifying Individual), Sharon A. Gunter, Director.

Airport Clearance Service, Inc. dba ACS Lines, 100 Lighting Way, Ste. 4000, Secaucus, NJ 07094, Officers: Jose I. Quesada, Dir. Global Pricing and Compliance (Qualifying Individual), Brian Posthumus, CEO.

Expeditionary Global Logistics, LLC dba Forward Express, 1900 Westridge Drive, Ste. 200, Irving, TX 75038, Officers: Rebecca L. Wibbeler, Member (Qualifying Individual), Hussen M. Haidar, Member.

Danesi USA, Inc., 7500 NW. 25th Street, Ste. 284, Miami, FL 33122, Officers: Jennifer Suarez, Manager (Qualifying Individual), Andrea Danesi, Director.

Marshal Freight Inc. dba Marshal Global, 6030 Riverside Drive, Ste. E, Chino, CA 91710, Officers: Jerick Cortes, CEO (Qualifying Individual), Maria Valderrama, President.

Dedicated Global Carriers, LLC, 4627 Town N. Country Blvd., Tampa, FL 33615, Officers: Robert J. Menendez, Manager (Qualifying Individual), Danny Mills, Vice President.

DGS Logistics, LLC dba DGS Ocean, 36 Evelyn Lane, Syosset, NY 11791, Officer: Patrick Jacob, Managing Member (Qualifying Individual).

Base Ventures Shipping dba Base Ventures International, 1405 Silver Lake Rd., NW., Ste. 201, New Brighton, MN 55112, Oluwaseyi Olawore, Sole Proprietor.

James J. Boyle & Co. dba JJB Link Logistics Company, Limited dba JJB Inland Logistics dba JJB Global, Logistics Co. Ltd., 1097 Sneath Lane, San Bruno, CA 94066, Officers: Greg Kodama, President (Qualifying Individual), Edward H. Inouye, CEO.

Oceanair Forwarding, Inc., 11232 St. Johns Ind Pkwy North, Ste. 6, Jacksonville, FL 32246, Officers: Philipus Suarto, Vice President (Qualifying Individual), Martin Pluis, President.

Chaucer Freight LLC, 909 AEC Drive, Wood Dale, IL 60191, Officer: Kathy Orzechowski, Operations Dir., (Qualifying Individual).

Newskin Express, Inc. dba NSK Logistics, Inc., 400 Crenshaw Blvd., Ste. 109, Torrance, CA 90503. Officer: Soo Jin Rho, President (Qualifying Individual).

Ocean Wings Logistics, Inc. dba LL Lines, 3340C Greens Rd., Ste. 555, Houston, TX 77032, Officers: Maria R. Banuelos, Secretary (Qualifying Individual), Thomas S. Passarra, President.

Navivan Corp., 200 Crofton Road, Ste. 2, Bldg. 10–B, Kenner, LA 70062, Officer: Ivan Lopez, President (Qualifying Individual).

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants:

Cabell Export LLC dba Cabell Export, 6125 Bay Pond Road, Ravenel, SC 29470, Officer: Kathryn E. Hardee, Member (Qualifying Individual).

Sahbell International Services, 18174 Riversage Dr., Ste. 120, Houston, TX 77084, Saheed Bello, Sole Proprietor.

Barinco International Corp., 5777 W. Century Blvd., Ste. 990, Los Angeles, CA 90045, Officer: Kathleen Howden, President (Qualifying Individual).

UPS Supply Chain Solutions, Inc. dba Menlo Worldwide Forwarding, 12380 Morris Road, Alpharetta, GA 30005, Officers: Jimmy Crabbe, Vice President (Qualifying Individual), Christine Callahan, COO.

Eriksson Classics, Inc., 3002 FM 517 E, Dickinson, TX 77539, Officer: Niklas Carl-Erik Eriksson, President (Qualifying Individual).

Dated: November 30, 2009.

Karen V. Gregory,

Secretary.

[FR Doc. E9–28884 Filed 12–2–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0330]

Determination That ABILIFY DISCMELT (Aripiprazole) Orally Disintegrating Tablets, 20 Milligrams and 30 Milligrams, 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 ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 milligrams (mg) and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for aripiprazole orally disintegrating tablets, 20 mg and 30 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, 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 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs 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 generally known 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 (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, are the subject of approved NDA 21–729 held by Otsuka Pharmaceutical Company, Limited (Otsuka). ABILIFY (aripiprazole) is indicated for the treatment of schizophrenia, for the acute and maintenance treatment of manic and mixed episodes associated with bipolar I disorder, as an adjunctive therapy to either lithium or valproate for the acute treatment of manic and mixed episodes associated with bipolar I disorder, for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder, for the treatment of irritability associated with autistic disorder, and for the acute treatment of agitation associated with schizophrenia or bipolar I disorder, manic or mixed.

FDA approved the NDA for ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, including the 20-mg and 30-mg strengths, on June 7, 2006. Otsuka has never marketed the 20-mg and 30-mg strengths of ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, and the 20-mg and 30-mg strength orally disintegrating tablets are listed in the ''Discontinued Drug Product List'' of the Orange Book.

Rakoczy Molino Mazzochi Siwik LLP submitted a citizen petition dated May 29, 2008 (Docket No. FDA–2008–P–0330), under 21 CFR 10.30, requesting that the agency (1) determine that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were discontinued from sale for reasons unrelated to safety and efficacy and (2) accept ANDAs for aripiprazole orally disintegrating tablets, 20 mg and 30 mg, and determine that such ANDAs are eligible for approval if all other legal and regulatory requirements are met. After considering the citizen petition and reviewing agency records, FDA has determined that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. To date, Otsuka has not marketed ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg. In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The petitioner identified no data or other information suggesting that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale as a result of safety or effectiveness concerns. FDA has reviewed its files for records concerning the withdrawal of ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg. There is no indication that Otsuka's decision not to market ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, commercially is a function of safety or effectiveness concerns, and no information has been submitted to the docket concerning the reason for which ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, 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 ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: November 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28871 Filed 12–2–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0560]

Determination That MESANTOIN (Mephenytoin) Tablets, 100 Milligrams, 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 MESANTOIN (mephenytoin) Tablets, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mephenytoin tablets, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, 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 (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs.