

Chung J. Park, President, Application Type: QI Change.
Your Connexion, Inc. (NVO & OFF), 13280 SW 131 Street, #108, Miami, FL 33186, Officers: Mauricio R. Valencia, President (Qualifying Individual), Mauricio J. Valencia, Secretary, Application Type: New NVO & OFF License.

Dated: August 10, 2012.

By the Commission.

Karen V. Gregory,
Secretary.

[FR Doc. 2012-20080 Filed 8-15-12; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

The Commission gives notice that the following Ocean Transportation Intermediary license has been reissued pursuant to section 40901 of the Shipping Act of 1984 (46 U.S.C. 40101).
License No.: 023327N.

Name: G & F West Indies Shipping, Inc.

Address: 1416 Blue Hill Avenue, Boston, MA 02125.

Date Reissued: June 26, 2012.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012-20079 Filed 8-15-12; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 40901 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 009931N.

Name: Westwind Transportation Services, Inc. dba Westwind Container Line.

Address: 1225 West 190th Street, Suite 300, Gardena, CA 90248.

Date Revoked: July 16, 2012.

Reason: Failed to maintain a valid bond.

License No.: 022365F.

Name: IVI Freight Systems Inc.

Address: 9112 NW 120th Terrace, Hialeah Gardens, FL 33018.

Date Revoked: July 28, 2012.

Reason: Failed to maintain a valid bond.

License No.: 022773F.

Name: WLI (USA) Inc.

Address: 175-01 Rockaway Blvd., Suite 228, Jamaica, NY 11434.

Date Revoked: July 15, 2012.

Reason: Failed to maintain a valid bond.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2012-20081 Filed 8-15-12; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on October 15, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2528, Silver Spring, MD 20993-0002, 301-796-9001, FAX 301-847-8533, email: GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a

previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will provide advice and recommendations to the Agency on the need for and design of clinical development programs necessary to support approval of parenteral lipid emulsion products as nutritional support.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 28, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 20, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 21, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20103 Filed 8-15-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on October 18, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, (301) 796-9001, Fax: (301) 847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203568, mipomersen injection, by Genzyme Corporation. The proposed indication (use) is as an adjunct to maximally tolerated lipid-lowering medications and diet to reduce low-density lipoprotein (LDL) cholesterol, apolipoprotein B, total cholesterol, non-high density lipoprotein-cholesterol and lipoprotein (a) in patients with homozygous familial hypercholesterolemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 2, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed

participants, and an indication of the approximate time requested to make their presentation on or before September 24, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 25, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20104 Filed 8-15-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endpoints for Clinical Trials in Kidney Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the endpoints for clinical trials of drugs and therapeutic biologics in kidney transplantation. This public workshop is intended to provide information and gain perspective from health care providers, academia, and industry on the role of various clinical, laboratory, histologic, genomic/proteomic, safety, and other endpoints