DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 18 2010 2010 AUG 20 A 11:33

Joan Janulis
Director
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Re: Docket No. FDA-2006-P-0386

Dear Ms. Janulis:

This letter responds to your citizen petition received on May 16, 2006, requesting that the Food and Drug Administration (FDA) determine whether DIASTAT (diazepam rectal gel), 5 milligrams (mg)/milliliter (mL), 10 mg/2 mL, 15 mg/3 mL and, 20 mg/4 mL, was withdrawn from sale for reasons of safety or effectiveness.[1] DIASTAT (diazepam rectal gel) is the subject of new drug application (NDA) 20-648, held by Valeant Pharmaceuticals International, and was initially approved on July 29, 1997.

The FDA has reviewed its records and determined that DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, in the "Discontinued Drug Product List" section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, do not hesitate to contact me at (301) 796-3507.

Sincerely,

for Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

[1] This citizen petition was originally assigned docket number 2006P-0209/CP1. The number was changed to FDA-2006-P-0386 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

FDA-2006-P-0386

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identified with Docket No. FDA–2010–N–0139 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 10, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–20418 Filed 8–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–P–0386]

Determination That DIASTAT (Diazepam Rectal Gel), 5 Milligrams/Milliliter, 10 Milligrams/2 Milliliter, 15 Milligrams/3 Milliliter, and 20 Milligrams/4 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) has determined that DIASTAT (diazepam rectal gel) (DIASTAT), 5 milligrams (mg)/milliliter (mL), 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 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 diazepam rectal gel, 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, 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 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 typically 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 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)(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.

Lachman Consultant Services, Inc., submitted to FDA a citizen petition dated May 15, 2006 (Docket No. FDA–2006–P–0386),[1] under 21 CFR 10.30 requesting that the agency determine whether DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was withdrawn from sale for reasons of safety or effectiveness. DIASTAT (diazepam rectal gel) is the subject of approved NDA 20–648 held by Valeant Pharmaceuticals International (Valeant) (formerly held by Xcel Pharmaceuticals). DIASTAT (diazepam rectal gel) is an anticonvulsant agent indicated for use in the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity.

DIASTAT (diazepam rectal gel) was approved on July 29, 1997 (NDA 20–648). On September 15, 2005, FDA approved a supplement (NDA 20–648/S–008) for a new delivery system of DIASTAT (diazepam rectal gel), marketed under the trade name DIASTAT ACUDIAL. Following approval of DIASTAT ACUDIAL, Valeant discontinued marketing DIASTAT (diazepam rectal gel) (NDA 20–648) in the 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL strengths, and those strengths of the product were moved to the "Discontinued Drug Product List" section of the Orange Book. We note that the original DIASTAT (diazepam rectal gel) and DIASTAT ACUDIAL that replaced the original DIASTAT delivery system contain the same diazepam gel formulation. Thus, the original diazepam gel formulation is still being marketed, but in a different delivery system.

After considering the citizen petitions, other information submitted to the docket, and reviewing our records, FDA has determined that DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was not withdrawn from sale 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 DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was withdrawn from sale for reasons of safety or effectiveness. Issues regarding the appropriateness of permitting ANDAs referencing the discontinued DIASTAT (diazepam rectal gel) to be marketed at the same time as DIASTAT ACUDIAL are being addressed in a separate docket (FDA–2006–P–0009).

Accordingly, the agency will continue to list DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 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 DIASTAT (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 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.

[1] This citizen petition was originally assigned docket number 2006P–0209. The number changed to FDA–2006–P–0386 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

Dated: August 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–20327 Filed 8–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its sixty-sixth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times:

September 15, 2010, 8:45 a.m.–5 p.m.

September 16, 2010, 8:45 a.m.–4 p.m.

September 17, 2010, 8:45 a.m.–11:15 a.m.

Place: Ox Yoke Inn, 4420 220th Trail, Amana, Iowa 52203. *Phone:* 319–622–3441.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Wednesday morning, at 8:45 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The first two presentations will be overviews of rural Iowa and the Iowa State Office of Rural Health. The remainder of the day the Committee will hear presentations on the three chosen Subcommittee topics. The first panel will focus on Childhood Obesity in Rural Communities. The second panel is Quality Implications of the Affordable Care Act. The final panel of the day is Rural Early Childhood Development Place-Based Initiatives. After the panel discussions, the Committee Chair will give an overview of the site visits. This will be followed by a call for public comment. The Monday meeting will close at 5 p.m.

Thursday morning, at 8:45 a.m., Tom Morris, Associate Administrator for Rural Health Policy, will provide a Departmental Update. At 9:15 a.m., the Committee will break into Subcommittees and depart to the site visits. The Childhood Obesity Subcommittee will visit Kids Corner in Tama County, IA and the Rural Early Childhood Development Place-Based Initiatives Subcommittee will visit the Pick A Better Snack Program at Walterboro Elementary in Walterboro, IA. The Quality Implications of the Affordable Care Act Subcommittee will visit a rural hospital, Grinnell Regional Medical Center. The Subcommittees will return to the Ox Yoke Inn in Amana at 3:30 p.m. Transportation to the site visits will not be provided to the public. The Tuesday meeting will close at 4 p.m.

The final session will be convened on Friday morning at 8:45 a.m. The meeting will open with a review of the Subcommittee site visits. The Chair of the Committee will lead a Working Session to discuss development of the Report to the Secretary. The Committee will draft a letter to the Secretary and discuss the February 2011 meeting. The meeting will be adjourned at 11:15 a.m.

For Further Information Contact: Thomas Morris, MPA, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 10B–45, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Jennifer Chang at the Office of Rural Health Policy (ORHP) via Telephone at (301) 443–0835 or by e-mail at *jchang@hrsa.gov*. The Committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: August 12, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–20424 Filed 8–17–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Pregnancy, Neonatology, and Nutrition.

Date: September 7–8, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, *sheardn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Diabetes and Endocrinology.

Date: September 13, 2010.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, *knechtm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Social Sciences and Population Studies.

Date: September 22, 2010.

Time: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Denise Wiesch, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, (301) 435–0684, *wieschd@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Brain Injury and Neurovascular Pathologies Study Section.

Date: September 27–28, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Alexander Yakovlev, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 11, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–20423 Filed 8–17–10; 8:45 am]

BILLING CODE 4140–01–P