Injection in the **Federal Register** of November 7, 2007 (72 FR 62858).)

Application No.	Drug	Applicant
NDA 6–799	RUBRAMIN PC (cyanocobalamin) Injection, 1 milligram (mg)/milliliter (mL)	Bristol Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 10–060	FLORINEF (fludrocortisone acetate) Tablets, 0.1 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
NDA 11–613	IONAMIN (phentermine resin complex) Extended-Release Capsules, equivalent to (EQ) 15 mg and 30 mg base	UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080
NDA 17–849	BRETHINE (terbutaline sulfate) Tablets, 2.5 mg and 5 mg	AAIPharma, LLC, 2320 Scientific Park Dr., Wilmington, NC 28405
NDA 17–970	NOLVADEX (tamoxifen citrate) Tablets, EQ 10 mg and 20 mg base	AstraZeneca Pharmaceuticals, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355
NDA 19–058	TENORMIN (atenolol) Injection, 0.5 mg/mL	Do.
NDA 19–645	TORADOL (ketorolac tromethamine) Tablets, 10 mg	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
NDA 19–778	PRINZIDE (hydrochlorothiazide and lisinopril) Tablets, 25mg/20mg	Merck Research Laboratories, P.O. Box 1000, IG2C–50, North Wales, PA19454–1009
NDA 19–816	ORUVAIL (ketoprofen) Extended-Release Capsules, 100 mg, 150 mg, and 200 mg	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 19–880	PARAPLATIN (carboplatin) for Injection, 50 mg/vial, 150 mg/vial, and 450 mg/vial	Bristol Myers Squibb Co.
NDA 50–582	DORYX (doxycycline hyclate) Delayed-Release Capsules, EQ 75 mg and 100 mg base	F.H. Faulding and Co., c/o Warner Chilcott, Inc., Rockaway 80 Corporate Center, 100 Enterprise Dr., suite 280, Rockaway, NJ 07866

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. 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: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30154 Filed 12–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0118]

Guidance for Industry on Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes.'' This guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk. We are issuing this guidance for immediate implementation to ensure that relevant issues related to minimizing cardiovascular risk are considered by all sponsors who have ongoing drug development programs for type 2 diabetes.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit

electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mary Parks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3362, Silver Spring, MD 20993–0002, 301–796–2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes.'' Diabetes mellitus is associated with an increased risk of cardiovascular disease. Reducing long-term cardiovascular complications in patients with diabetes should be an important goal of disease management. There are compelling data in patients with type 2 diabetes supporting a reduced risk of microvascular complications with improved long-term glycemic control. This guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk.

On March 3, 2008, FDA issued the draft guidance for industry entitled ''Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention'' (73 FR 11420). On July 1 and 2, 2008, the Endocrinologic and Metabolic Drugs Advisory Committee met to discuss the role of cardiovascular assessment in the premarketing and postmarketing settings for drugs and therapeutic biologics developed for the treatment of type 2 diabetes mellitus. After considering the discussion at this meeting as well as other available data and information, we have determined that concerns about cardiovascular risk should be more thoroughly addressed during drug development. We are issuing this guidance to ensure that our recommendations reach all sponsors who may submit applications for approval of drugs to treat type 2 diabetes mellitus.

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is not seeking comment before implementing this guidance because of the need to immediately notify sponsors with ongoing development programs of the need to address cardiovascular risk in ongoing drug development programs. If FDA receives comments on this guidance, it will consider the comments and incorporate final recommendations into the final version of the March 2008 draft guidance.

This guidance represents the agency's current thinking on evaluating cardiovascular risk in new antidiabetic therapies to treat type 2 diabetes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014, and the collections of information in 21 CFR part 314 have been approved under 0910–0001.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: December 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30086 Filed 12–17–08; 11:15 am]

BILLING CODE 4160–01–S

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. Appendix 2), 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, Prevention, Interventions: Alcohol, Diabetes and Smoking.

Date: January 6, 2009.

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: Anna L. Riley, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Member Conflicts in Microbiology.

Date: January 8–9, 2009.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Guangyong Ji, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–1146.

This notice is being published less than 15 days prior to the meeting due to the timing