

end of FY 2013, FDA estimates that 490 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 20 establishment fee waivers or reductions will be made for FY 2013. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 35 establishments (20 waivers, plus the estimated 15 establishments under the orphan exemption) from 490 leaves a net of 455 fee-paying establishments. FDA will use 455 for its FY 2014 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments (\$252,342,667) by the estimated 455 establishments, for an establishment fee rate for FY 2014 of \$554,600 (rounded to the nearest \$100).

B. Product Fees

At the beginning of FY 2013, the product fee was based on an estimate that 2,435 products would be subject to and would pay product fees. By the end of FY 2013, FDA estimates that 2,510 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 45 waivers and reductions granted. In addition, FDA estimates that another 40 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,425 products will qualify for product fees in FY 2013, after allowing for waivers and reductions, including the orphan drug products, and will use this number for its FY 2014 estimate. The FY 2014 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$252,342,667) by the estimated 2,425 products for a FY 2014 product fee of \$104,060 (rounded to the nearest \$10).

V. Fee Schedule for FY 2014

The fee rates for FY 2014 are set out in table 7 of this document:

TABLE 7—FEE SCHEDULE FOR FY 2014

Fee category	Fee rates for FY 2014
Applications: Requiring clinical data	\$2,169,100
Not requiring clinical data	
	1,084,550

TABLE 7—FEE SCHEDULE FOR FY 2014—Continued

Fee category	Fee rates for FY 2014
Supplements requiring clinical data	1,084,550
Establishments	554,600
Products	104,060

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received after September 30, 2013. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197-9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact the U.S. Bank at 314-418-4013 if you have any questions concerning courier delivery.)

Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

Wire transfer payment may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Drive, Rockville, MD.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of FDA is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2014 under the new fee schedule in August 2013. Payment will be due on October 1, 2013. FDA will issue invoices in November 2014 for any products and establishments subject to fees for FY 2014 that qualify for fee assessments after the August 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0869]

Pfizer, Inc.; Withdrawal of Approval of a New Drug Application for BEXTRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for BEXTRA (valdecoxib) 10 milligram (mg) and 20 mg Tablets, held by Pfizer, Inc. (Pfizer), 235 East 42nd St., New York, NY 10017-5755. Pfizer has voluntarily requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Effective August 2, 2013.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA approved BEXTRA (valdecoxib) 10 mg and 20 mg Tablets on November 16, 2001. BEXTRA is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis and for the treatment of primary dysmenorrhea. On April 7, 2005, FDA announced that it had concluded that the overall risk versus benefit profile of BEXTRA was unfavorable and that it had asked Pfizer to voluntarily withdraw BEXTRA from the market. Pfizer agreed and voluntarily suspended all sales and marketing of BEXTRA on July 21, 2005. In letters dated May 27, 2011, August 8,

2011, and October 31, 2011, Pfizer requested that FDA withdraw approval of NDA 21–341 for BEXTRA. In the letter dated October 31, 2011, Pfizer waived any opportunity for a hearing otherwise provided under 21 CFR 314.150 (§ 314.150). In FDA's letter of November 9, 2011, responding to Pfizer's letters dated May 27, 2011, August 8, 2011, and October 31, 2011, the Agency acknowledged Pfizer's request to withdraw approval of BEXTRA under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21–341, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 30, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education; Cooperative Agreement Program

Announcement Type: Limited New and Competing Continuation
Funding Announcement Number: HHS–2013–IHS–NIHOE–0001
Catalog of Federal Domestic Assistance Number: 93.933

Key Dates

Application Deadline Date: September 6, 2013
Review Date: September 10, 2013
Earliest Anticipated Start Date: September 30, 2013
Proof of Non-Profit Status Due Date: September 6, 2013

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the National Indian Health Outreach and Education

(NIHOE) I limited competition cooperative agreement program. This award includes the following four components, as described in this announcement: “Line Item 128 Health Education and Outreach funds,” “Health Care Policy Analysis and Review,” “Budget Formulation” and “Tribal Leaders Diabetes Committee” (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

Background

The NIHOE program carries out health program objectives in the American Indian and Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. This program requires that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. This program also requires that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS based on Tribal input through a broad based consumer network.

Purpose

The purpose of this IHS cooperative agreement is to further IHS's mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. This award includes the following four health services components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and Tribal Leaders Diabetes Committee (TLDC).

Limited Competition Justification

Competition for the award included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will

have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between the Department of Health and Human Services (HHS) and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year 2013 is approximately \$716,000. Three hundred thousand dollars (\$300,000) is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal Shares with the IHS (this amount could vary based on Tribal Shares assumptions; Line Item 128 Health Education and Outreach funding will be awarded in partial increments based on availability and amount of funding); \$100,000 for the Health Care Policy Analysis and Review; \$16,000 for the Budget Formulation; and \$300,000 associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI). All competing and continuation awards