Estimated Total Annual Burden Hours: 521,449

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2013–17331 Filed 7–18–13; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0815]

Narcolepsy Public Meeting on Patient-Focused Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting: request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for narcolepsy. Patient-Focused Drug Development is part of FDA’s performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients’ perspectives on the impact of narcolepsy on daily life as well as the available therapies for narcolepsy.

DATES: The public meeting will be held on September 24, 2013, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by September 13, 2013. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting. Submit electronic or written comments by November 25, 2013.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm359018.htm.


SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected narcolepsy to be the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients’ perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA’s performance commitments made as part of the authorization of PDUFA under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients’ daily lives, the types of treatment benefit that matter most to patients, and patients’ perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the Federal Register (78 FR 22613) announcing the disease areas for meetings in fiscal years (FY) 2013–2015, the first 3 years of the 5-year PDUFA V timeframe. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency gathered public comment on these criteria and potential disease areas through a notice for public comment published in the Federal Register on September 24, 2012 (77 FR 55849), and through a public meeting...
3.1. Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

3.2. How well do these therapies work for you as your condition has changed over time?

3.3. What are the most significant downsides to your current therapies, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, inconvenient dosing schedules, access issues, etc.)

3.4. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal therapy for your condition?

B. Meeting Attendance and/or Participation

If you wish to attend this meeting, visit http://patientfocusednarcolepsy.eventbrite.com. Please register by September 13, 2013. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send a brief summary of responses to the topic questions to PatientFocused@fda.hhs.gov. Panelists will be notified of their selection soon after the close of registration on September 13, 2013. FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see ADDRESSES). Comments may be submitted until November 25, 2013.

Dated: July 15, 2013.

Leslie Kux, Assistant Commissioner for Policy.

[FR Doc. 2013–17327 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0845]

Bracco Diagnostics et al.; Withdrawal of Approval of 52 New Drug Applications and 77 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 52 new drug applications (NDAs) and 77 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective August 19, 2013.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in...