ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Program Information Report	3,041	1	4	12,164
Grantee Monthly Enrollment Reporting	1,773	12	0.05	1,063.8
Contacts, Locations & Reportable Conditions	3,041	1	0.25	760.25

Estimated Total Annual Burden Hours: 13,988.05.

Additional Information:

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–17654 Filed 7–25–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0723]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Reports of Corrections and Removals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 8, 2014, the Agency submitted a proposed collection of information entitled ''Medical Devices; Reports of Corrections and Removals'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0359. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17633 Filed 7–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0079]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Animal Generic Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Animal Generic Drug User Fee Cover Sheet'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 28, 2014, the Agency submitted a proposed collection of information entitled ''Animal Generic Drug User Fee Cover Sheet'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0632. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17712 Filed 7–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1008]

Exploring the Possibility of Proprietary Name Reservation for Drug Products; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to discuss issues related to reserving proprietary names for drug products. During the negotiations for the 2007 reauthorization of the Prescription Drug User Fee Amendments Act (PDUFA IV), FDA agreed to several performance goals related to the review of drug and biological product proprietary names to reduce medication error. Among those goals, FDA and industry expressed an

interest in exploring the possibility of ''reserving'' proprietary names for companies once the names have been tentatively accepted by the Agency. Accordingly, FDA is initiating a public process to discuss issues around reserving proprietary names.

DATES: Submit electronic or written comments by October 27, 2014.

ADDRESSES: Submit electronic comments to *http://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.

FOR FURTHER INFORMATION CONTACT: Kellie Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–0157, *Kellie.Taylor@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Proprietary Name Review Activities Under PDUFA IV

In conjunction with the 2007 reauthorization of PDUFA IV, FDA agreed to a number of performance goals related to the Agency's review of drug and biological product proprietary names to reduce medication error. For the first time, the Agency agreed to a process and timelines for notifying applicants of the tentative acceptance or nonacceptance of a proposed proprietary name. These proprietary name review performance goals and timelines are separate from the timelines for approval of underlying new drug applications and biologics license applications. These goals and timelines also permit sponsors or applicants to obtain such a notification as early as during the investigational new drug stage, any time after the completion of a Phase II study.

Pursuant to related PDUFA IV goals, the Agency also undertook several other measures intended to provide additional transparency regarding the methods and tools that FDA uses in considering whether a proposed proprietary name is likely to contribute to medication error or otherwise render the drug misbranded. (*See,* for example, Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf* PDUFA Pilot Project, Proprietary Name Review, Concept Paper, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072229.pdf* and *http://www.gpo.gov/fdsys/pkg/FR-2009-02-17/pdf/E9-3170.pdf.*) The guidance on Contents of a Complete Submission for the Evaluation of Proprietary Names also lays out the legal basis for FDA's review of drug proprietary names, derived from its authority over labeling and the requirements for product approval.

In accordance with the performance goals described above, since fiscal year (FY) 2008, FDA has provided a mechanism for applicants to be notified that the Agency considers a proprietary name to be unacceptable before final approval of the underlying product application. This process enables applicants to plan more effectively for postapproval marketing, for example, by seeking reconsideration of a proposed proprietary name that FDA considers problematic or by proposing an alternative name. However, because the ultimate approval of a proprietary name comes as part of the approval of the drug labeling, and thus is not final until the approval of a marketing application, the positive outcome of a proprietary name review that is completed before application approval is limited to a tentative acceptance of that name. It is possible that a name judged tentatively acceptable may later be found unacceptable for a number of reasons, including, for example, the intervening entry into the U.S. market of another product with a confusingly similar name, changes in the product's characteristics during review, or new information about the likelihood of error arising from postmarketing data about another product.

Stakeholders have indicated that the existing process does not provide applicants with sufficient certainty, prior to approval of their application, that a proposed proprietary name will be included in approved drug labeling. Some members of industry have suggested that they remain particularly concerned that a ''tentatively acceptable'' name may be subsequently rejected because of the intervening approval of another drug whose application was pending, but not public, at the same time as their own. In the documentation regarding its pilot program for proprietary name review, FDA acknowledged that it may be unable to disclose certain information to an applicant in connection with a proprietary name review. (*See* PDUFA Pilot Project, Proprietary Name Review, Concept Paper at 31–32, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072229.pdf.*) (''[I]n some cases FDA has access to information that is not publicly available to applicants.'').

In such cases, FDA will communicate with the applicant to the extent permitted by law to describe the nature of this information. One example of this is where other proprietary names are being considered by the Agency at the same time, and the Agency believes that the proposed names would be likely to cause confusion or medication error. Under FDA's regulations, information in an unapproved application, including proposed proprietary names, is generally not publicly available (*see* 21 CFR 312.130, 314.430, 601.50, and 601.51). In such situations, FDA generally notifies applicants that their proposed proprietary name could result in medication errors due to confusion with another product that is also under review and informs the applicant that acceptability of a proposed proprietary name may be affected by prior approval of the other product.

B. Current Action: Establishment of a Public Docket To Discuss Issues Around ''Reserving'' Proprietary Names for Drugs

FDA is now establishing a public docket in furtherance of the following additional proprietary name review-related performance goal, contained in the PDUFA IV goals letter:

''FDA and industry are interested in exploring the possibility of ''reserving'' proprietary names for companies once the names have been tentatively accepted by the Agency. By the end of FY 08, FDA will initiate a public process to discuss issues around ''reserving'' proprietary names.''

In January 2009, staff from FDA met with representatives from the Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss the proposed program. At that time, PhRMA offered to submit a draft guidance for comment. PhRMA did submit a draft guidance entitled ''Early Review of Proprietary Names'' to FDA for consideration. FDA has placed PhRMA's proposed guidance document in the newly established public docket for information pertaining to a possible name reserve program, so that it is available to all interested members of the public.

II. Comments

Interested persons may submit either written comments to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

FDA invites comment on all matters relating to a potential program for reserving proprietary names for drug products. This request is not limited to comments on the proposal described in the submission by PhRMA. FDA is particularly interested in comments and information regarding the following:

- Are there examples of drug market launches being delayed, or of drugs being launched without a proprietary name, because FDA's determination that a proposed proprietary name would not be acceptable came too close to the date of product approval? If so, please provide details, including how far in advance of approval the applicant submitted the proposed name to the Agency, whether the proposed name had been tentatively accepted, and how long the launch was delayed or how long the product was marketed without a proprietary name.
- Potential approaches for reserving proprietary names that would create more certainty for applicants than the current ''tentative acceptance'' process. For each proposed approach, please describe the following:
  - How the program would create certainty while balancing the need to avoid or minimize the risk of medication error.
  - The parameters of the proposed program, including whether participation in the program should be voluntary or mandatory; what conditions should be met before a name is ''reserved''; and for how long a name may be ''reserved.''
  - The procedural and legal framework for the proposed program.
  - Whether the ''reservation'' of a proprietary name for one applicant would be binding, such that a similar or identical proprietary name for another applicant's drug would be rejected, even in situations in which such drug is ready for approval before that of the applicant for whom the name is ''reserved.''
  - A discussion of the application of the program to over-the-counter monograph products and drugs that are manufactured for a private label distributor, under an existing approved application.
- Data and information regarding:
  - The number of applicants that would be interested in participating in a voluntary name reservation program.
  - Whether applicants would be willing to participate voluntarily if ''reservation'' of a name is not guaranteed to prevent the use of the name by all other drugs that enter the U.S. market prior to the drug for which the name is ''reserved.''
- In the absence of a binding name reservation program, what measures could be used to provide greater predictability to applicants about the likelihood that a name found tentatively acceptable will subsequently be approved? Can industry address this without FDA involvement, for example, through a voluntary posting of proposed names?
- Under current FDA regulations, information in an unapproved application, including proposed proprietary names, is generally not publicly available (*see* 21 CFR 312.130, 314.430, 601.50 & 601.51). What mechanisms could be used to provide notice to an applicant of possible confusion between its proposed proprietary name and other proposed proprietary names contained in pending applications?

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17691 Filed 7–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0652]

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].'' This guidance document describes FDA's current review practices for premarket notification (510(k)) submissions by describing in greater detail the regulatory framework, policies, and practices underlying FDA's review of traditional 510(k) submissions. This guidance document does not address the special and abbreviated 510(k) programs. FDA intends to finalize those sections separately.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marjorie Shulman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1536, Silver Spring, MD 20993–0002, 301–796–6572; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance serves to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence under the 510(k) program. Since the program's inception in 1976, FDA has periodically published documents, including guidance