during Phase 2 will also be used to assess the differences in services used between families who receive home visiting and a comparison group.

Respondents: Respondents in Phase 2 will include parents and children who are enrolled in the study. Data collection activities will take place over a three-year period.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Survey of parents in the study	1360	1	1.0	1360
Observed parent-child interactions	2720	1	0.5	1360
Direct assessments of children	2720	1	0.7	1904
Collecting saliva to measure cotinine	2720	1	0.1	272
Estimated Total Annual Burden Hours				4896

In compliance with the requirements of Section 3506(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: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–18702 Filed 7–31–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0813]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in FDA's regulations on postmarketing reporting of information pertaining to drug shortages.

DATES: Submit either electronic or written comments on the collection of information by October 1, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information 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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information [,including each proposed [extension/reinstatement] of an existing collection of information,] before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance (OMB Control Number 0910–0699)—Extension

FDA published an interim final rule on December 19, 2011 (76 FR 78530) amending its postmarketing reporting regulations implementing certain provisions of the Federal Food, Drug and Cosmetic Act. The provisions of the Federal Food, Drug and Cosmetic Act require manufacturers who are the sole manufacturers of certain drug products to notify FDA at least 6 months before discontinuance of manufacture of the products. The interim final rule modified the term ''discontinuance'' and clarified the term ''sole manufacturer'' with respect to notification of discontinuance requirements. The broader reporting resulting from these changes will enable FDA to improve its collection and distribution of drug shortage information to physician and patient organizations and to work with manufacturers and other stakeholders to respond to potential drug shortages.

Sections 314.81(b)(3)(iii) and 314.91 of FDA's regulations implement section 506C of the Federal Food, Drug and Cosmetic Act. Section 314.81(b)(3)(iii) requires entities who are the sole manufacturers of certain drug products to notify us at least 6 months before discontinuance of manufacture of the product. For the regulations to apply, a product must meet the following three criteria:

1. The product must be life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition;

2. The product must have been approved by FDA under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act; and

3. The product must not have been originally derived from human tissue and replaced by a recombinant product.

Under § 314.81(b)(3)(iii)(c), FDA will publicly disclose information about drug products subject to section 506C that are to be discontinued. Section 314.91 allows us to reduce the 6-month notification period if we find that good cause exists for the reduction. A manufacturer may request that we reduce the notification period by certifying that good cause for the reduction exists.

FDA added §§ 314.81(b)(3)(iii) and 314.91 to its regulations in the **Federal Register** of October 18, 2007 (72 FR 58993). Sections 314.81(b)(3)(iii) and 314.91 require two new reporting requirements to FDA that are subject to OMB approval under the PRA: Notification of Discontinuance and Certification of Good Cause. The December 19, 2011, interim final rule added two new definitions to § 314.81(b)(3)(iii): ''Discontinuance'' and ''sole manufacturer.'' The interim final rule clarified the scope of manufacturers required to report and expanded the range of circumstances required to be reported to the Agency under § 314.81(b)(3)(iii), but did not change the substantive content of the reports required to be submitted to the Agency. This PRA analysis covers the information collection resulting from the October 18, 2007, final rule and also includes estimates of how the number of Notifications of Discontinuance and Certifications of Good Cause may increase as a result of the interim final rule.

A. Notification of Discontinuance

Under § 314.81(b)(3)(iii), at least 6 months before a sole manufacturer intends to discontinue manufacture of a drug product subject to section 506C, the manufacturer must send us notification of the discontinuance. The notification of discontinuance generally contains the name of the manufacturer, the name of the product to be discontinued, the reason for the discontinuance, and the date of discontinuance. FDA will work with relevant manufacturers during the 6-month notification period to help minimize the effect of the discontinuance on patients and health care providers, and to distribute appropriate information about the discontinuance to physician and patient organizations. The interim final rule added definitions of ''discontinuance'' and ''sole manufacturer'' to § 314.81(b)(3)(iii). The inclusion of these definitions expands notification requirements under § 314.81(b)(3)(iii) to additional discontinuance circumstances and clarifies the scope of manufacturers who must report discontinuances. The interim final rule also required that notifications of discontinuance be submitted either electronically or by telephone according to instructions on FDA's Drug Shortage Web site at *http://www.fda.gov/Drugs/DrugSafety/DrugShortages*. This change ensures that the appropriate offices are timely notified of all relevant discontinuances. It also reflects existing practice for submitting notices of discontinuance, and reduces the burden on industry to submit multiple copies of the notification.

B. Certification of Good Cause

FDA may reduce the 6-month notification period if we find good cause for the reduction. As described in § 314.91, a manufacturer can request a reduction in the notification period by submitting written certification that good cause exists to the following designated offices: (1) The CDER Drug Shortage Coordinator at the address of the Director of CDER; (2) the CDER Drug Registration and Listing Team, Division of Compliance Risk Management and Surveillance in CDER; and (3) the director of either the CDER division or the CBER office that is responsible for reviewing the application. The following circumstances may establish good cause:

- A public health problem may result from continuation of manufacturing for the 6-month period (§ 314.91(d)(1));
- A biomaterials shortage prevents the continuation of manufacturing for the 6-month period (§ 314.91(d)(2));
- A liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period (§ 314.91(d)(3));
- Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer (§ 314.91(d)(4));
- The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (§ 314.91(d)(5));
- The manufacturer can stop making the product but still distribute it to satisfy existing market need for 6 months (§ 314.91(d)(6)); or
- Other good cause exists for a reduction in the notification period (§ 314.91(d)(7)).

With each certification described previously, the manufacturer must describe in detail the basis for its conclusion that such circumstances exist. We require that the written certification that good cause exists be submitted to the offices identified previously to ensure that our efforts to address the discontinuance take place in a timely manner. The interim final rule made no changes to the requirements or process for certification of good cause.

Description of Respondents: An applicant that is the sole manufacturer and who is discontinuing manufacture of a drug product that meets the following criteria: (1) Is life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition; (2) was approved by FDA under section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; and (3) was not originally derived from human tissue and replaced by a recombinant product.

Burden Estimate: The table below provides an estimate of the annual reporting burden for notification of a product discontinuance and certification of good cause under §§ 314.81(b)(3)(iii) and 314.91, as amended by the interim final rule.

Notification of Discontinuance: Based on data collected from the CDER Drug Shortage Coordinator since December 17, 2007, when §§ 314.81(b)(3)(iii) and 314.91 went into effect, one manufacturer during each year reported to FDA a discontinuance of one drug product meeting the criteria of section 506C and its implementing regulations (i.e., the drug product was approved under section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act, the drug product was ''life-supporting, life-sustaining or intended for use in the prevention of a debilitating disease or condition,'' the drug product was produced by a sole manufacturer, and the drug product was permanently discontinued). CDER's Drug Shortages Coordinator tracked 220 drug shortages between January and October of 2011. The Agency estimates that 30 percent (66) of these shortages would relate to discontinuances subject to mandatory reporting under section 506C as a result of the interim final rule. Adjusting to include an additional two months of reporting (November and December), we estimate that FDA will receive a total of 80 notifications of a discontinuance per year under section 506C, as amended by the interim final rule. Based on experience, a manufacturer submits only one notification of a discontinuance per year, thus the total number of manufacturers who would be required to notify us of a discontinuance would be 80. Therefore, the number of respondents is estimated to be 80. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a notification of product discontinuance, including the time it takes to gather and copy the statement. Based on experience in working with manufacturers to submit notifications under § 314.81(b)(3)(iii), we estimate that approximately 2 hours on average are needed per response. We do not expect the changes in the interim final rule to affect the number of hours per response. Therefore, we estimate that respondents will spend 160 hours per year notifying us of a product discontinuance under these regulations.

Certification of Good Cause: Based on data collected from the CDER drug shortage coordinator since 2007, one manufacturer each year reported a discontinuance of one drug product under section 506C and its implementing regulations. Each manufacturer has the opportunity under § 314.91 to request a reduction in the 6-month notification period by certifying to us that good cause exists for the reduction. The Agency has received no certifications of good cause since 2007. Although we expect we will receive an increase in the number of reports of discontinuances as a result of the changes in the interim final rule, because of the limited circumstances under which good cause can be requested or would be appropriately granted, we do not expect a correspondingly large increase in the number of manufacturers requesting a certification of good cause. We estimate that only 5 manufacturers will request a certification of good cause each year. Therefore, the number of respondents is estimated to be 5. The total annual responses are the total number of certifications of good cause that are expected to be submitted to us in a year. We estimate that the total annual responses will remain small, averaging one response per respondent. The hours per response is the estimated number of hours that a respondent spends preparing the detailed information certifying that good cause exists for a reduction in the notification period, including the time it takes to gather and copy the documents. We estimate that approximately 16 hours on average are needed per response. Therefore, we estimate that 80 hours will be spent per year by respondents certifying that good cause exists for a reduction in the 6-month notification period under § 314.91.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification of Discontinuance (314.81(b)(3)(iii)	80	1	80	2	160
Certification of Good Cause (314.91)	5	1	5	16	80
Total					240

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18771 Filed 7–31–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On March 29, 2012, the Agency submitted a proposed collection of information entitled ''Reclassification Petitions for Medical Devices'' to OMB for review