ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

| Respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|
| CDI Surveillance Case Report Form—Partial | 10 | 438 | 15/60 |
| CDI Surveillance Health Interview | 10 | 50 | 45/60 |

Dated: March 9, 2011.

**Carol Walker,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2011–5919 Filed 3–14–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Withdrawl of Publication

This is to serve notice that the following **Federal Register** notice published on March 1, 2011, page 11250, is being rescinded:

**Submission for OMB Review: Comment Request**

*Title:* Child Care and Development Fund Tribal Plan Preprint—ACF–118–A.

*OMB No.:* 0970–0198.

The original notice published on February 9, 2011, pages 7218–7219 is still in effect.

Dated: March 9, 2011.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011–5845 Filed 3–14–11; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0554]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by April 14, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0359. Also include the FDA docket number found in brackets in the heading of this document.

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Devices; Reports of Corrections and Removals—(OMB Control Number 0910–0359)—(Extension)**

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 301) (Pub. L. 105–115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

Respondents to this collection of information are manufacturers and importers of medical devices. FDA reviewed reports of device corrections and removals submitted to the Agency for the previous 3 years as part of responding to the current request for approval of the information collection requirements for §§ 806.10 and 806.20. This information was obtained through the Agency's voluntary recall provisions (*i.e.,* 21 CFR part 7). The specific information requested was the total number of class I, II, and III recalls for the last 3 years. This information was obtained from the Agency's Recall Enterprise System—a database of all recalls submitted to the Agency.

This information is relevant since a § 806.10 report is required for all class I and II recalls. Although class III recalls are not required to be submitted to FDA (by § 806.10), a record must be kept in the firm's § 806.20 file. Therefore, the number of class I and II recalls can be used to estimate the maximum number of reports that are required to be submitted under § 806.10. Also, the recordkeeping burden can be estimated based upon the number of class III recalls, which are not required to be reported, but must be retained in a § 806.20 file.

FDA has determined that estimates of the reporting burden for § 806.10 should be revised to reflect a projected 7.3 percent increase (from the last PRA numbers) in reports submitted to FDA as class I and II. FDA also estimates the recordkeeping burden in § 806.20 should be revised to reflect a reduction of 6.8 percent (from the last PRA numbers) in records filed and maintained under § 806.20. The estimates of time needed to collect part 806 information have not changed.

In the **Federal Register** of November 23, 2010 (75 FR 71446), FDA published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|---|---|---|---|---|---|
| 806.10 | 666 | 1 | 666 | 10 | 6660 |

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

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

| CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping (in hours) | Total hours |
|---|---|---|---|---|---|
| 806.20 | 90 | 1 | 90 | 10 | 900 |

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

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–5916 Filed 3–14–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–P–0177]**

### Determination that ROCEPHIN (Ceftriaxone Sodium) Injection, 250 Milligrams, 500 Milligrams, 1 Gram, 2 Grams, and 10 Grams Base/Vial, Approved Under New Drug Application 050585, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined ROCEPHIN (ceftriaxone sodium) Injection, 250 milligrams (mg), 500mg, 1 gram (g), 2g, and 10g base/vial, approved under new drug application (NDA) 050585, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for any of these products if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, are the subject of NDA 050585 held by F. Hoffman-La Roche Ltd. (La Roche). ROCEPHIN (ceftriaxone sodium) is a semisynthetic cephalosporin antibiotic for intravenous or intramuscular administration and is indicated for the treatment of certain infections as described in the labeling. The drug products approved under NDA 050585 are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Steven H. Sklar of Leydig, Voit & Mayer, Ltd., submitted a citizen petition dated April 3, 2009 (Docket No. FDA–2009–P–0177), under 21 CFR 10.30, requesting that FDA determine that ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, approved under NDA 050585, were withdrawn from sale for reasons other than safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, approved under NDA 050585, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these products from sale. We have also independently evaluated the relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that any of these products were