Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@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, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: October 28, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–24600 Filed 11–3–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Provision of Services in Interstate Child Support Enforcement: Standard Forms.

OMB No.: 0970–0085.

Description: Pub. L. 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, amended 42 U.S.C. 666 to require State Child Support Enforcement (CSE) agencies to enact the Uniform Interstate Family Support Act (UIFSA) into State law by January 1, 1998. Section 311(b) of UIFSA requires the States to use standard interstate forms, as mandated by Federal law. 45 CFR 303.7 also requires CSE programs to transmit child support case information on standard interstate forms when referring cases to other States for processing. During the OMB clearance process, we are taking the opportunity to make revisions that have been requested by the States.

Respondents: State agencies administering the Child Support Enforcement program under title IV–D of the Social Security Act.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal 1	54	19,278	.25	260,253
Transmittal 2	54	14,458	.08	62,459
Transmittal 3	54	964	.08	4,164
Uniform Petition	54	9,639	.08	41,640
General Testimony	54	11,567	.33	206,124
Affidavit Paternity	54	4,819	.17	44,238
Locate Data Sheet	54	375	.08	1,620
Notice of Controlling Order	54	964	.08	4,164
Registration Statement	54	8,675	.08	37,476

Estimated Total Annual Burden Hours: 662,138.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail address: *grjohnson@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, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._/Astrich@omb.eop.gov.*

Dated: October 27, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–24601 Filed 11–3–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N–1409]

Medical Devices; Reclassification of the Iontophoresis Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify those iontophoresis devices currently in class III (premarket approval) into class II (special controls). An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the proposed rule the agency issued in the **Federal Register** of August 22, 2000 (65 FR 50949) (the August 2000 proposed rule).

DATES: Submit written or electronic comments by February 2, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA issued a final rule classifying the iontophoresis device into class II (performance standards before the Safe Medical Devices Act of 1990 and now special controls) and class III (premarket approval), depending on its intended use. An iontophoresis device is a device

that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. If the iontophoresis device is intended for use in the diagnosis of cystic fibrosis or another intended use and the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, the device is categorized as class II. An iontophoresis device that is intended to introduce ions of soluble salts or other drugs into the body for other purposes is categorized as class III.

In the **Federal Register** of August 22, 2000, FDA proposed to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA proposed this action because it believed that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. FDA expected that manufacturers of those devices currently in class III would be able to relabel their devices to meet the class II identification.

In response to the August 2000 proposed rule, FDA received seven comments. Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. Two comments were confused as to whether the requirement that a drug used with an iontophoresis device bear adequate directions for use with that specific device applies to the diagnosis of cystic fibrosis or applies only to other uses. Two comments asserted that the assumption that there are differences in iontophoresis devices that would warrant linking a particular device to a particular drug is in error, and suggested that FDA should consider reclassification of iontophoresis devices into either class I or class II as drug delivery systems comparable to syringes and pumps. In contrast, another comment rejected what it perceived as the implication that all iontophoresis drug delivery systems were the same and that any iontophoresis device could be relabeled to reference any drug approved for iontophoretic administration, whether or not the drug had actually been tested for use with that particular device.

FDA is issuing this document to provide interested persons with an opportunity to submit any new information concerning the safety and effectiveness of the iontophoresis device. After FDA reviews any information that the agency receives in response to this document, FDA will decide whether the agency should go forward with the reclassification of those iontophoresis devices currently in class III and whether a panel meeting is necessary before taking any action.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Any received information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 25, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–24591 Filed 11–3–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0087]

Draft Guidance for Industry on Listed Drugs, 30-Month Stays, and Approval of Abbreviated New Drug Applications and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers.'' This draft guidance follows the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) (MMA) on December 8, 2003. In part, this guidance satisfies FDA's obligation under that law to clarify the definition of ''listed drug'' for persons who wish to submit a change (i.e., an amendment or supplement) to an abbreviated new drug application (ANDA). The guidance explains when a change to an application should reference a drug different from the drug listed in the original ANDA, requiring the change to be made through an entirely new application.

In addition to the definition of ''listed drug,'' the draft guidance clarifies certain other provisions of the MMA that significantly change the law that existed before the MMA's enactment. These include changes regarding 30-month stays and approval of ANDAs and new drug applications submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (505(b)(2) applications). The draft guidance also explains the effective dates that apply to the MMA's provisions.

DATES: Submit written or electronic comments on the draft guidance by February 2, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Shimer, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855 301–827–5710.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers.'' On December 8, 2003, the MMA was signed into law. Among other things, Title XI of that law, ''Access to Affordable Pharmaceuticals,'' states that guidance will be issued to define the term ''listed drug'' with respect to amendments and supplements to ANDAs. This guidance is necessary because the MMA specifies that, ''An