

Dated: June 13, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Information Comparison with Insurance Data.

OMB No.: 0970-0342.

Description

The Deficit Reduction Act of 2005 amended Section 452 of the Social Security Act (the Act) to authorize the Secretary, through the Federal Parent Locator Service (FPLS), to conduct

comparisons of information concerning individuals owing past-due child support with information maintained by insurers (or their agents) concerning insurance claims, settlements, awards, and payments. Public Law 109-171, § 7306. The Federal Office of Child Support Enforcement (OCSE) operates the FPLS in accordance with section 453(a)(1) of the Act. The Federal Case Registry of Child Support Orders (FCR) is maintained in the FPLS in accordance with section 453(h)(1) of the Act.

At the option of an insurer, the comparison may be accomplished by either of the following methods. Under the first method, an insurer or the insurer's agent will submit to OCSE information concerning claims, settlements, awards, and payments. OCSE will compare that information with information pertaining to individuals owing past-due support.

Under the second method, OCSE will furnish to the insurer or the insurer's

agent a file containing information pertaining to individuals owing past-due support. The insurer or the insurer's agent will compare that information with information pertaining to claims, settlements, awards, and payments. The insurer will furnish the information resulting from the comparison to OCSE.

On a daily basis OCSE will furnish the results of the comparison by transmitting the Insurance Match Response Record to the state agencies responsible for collecting past-due child support from the individuals. The results of the comparison will be used by the state agencies to collect past-due child support from the insurance proceeds.

Respondents

Insurers or their agents, including the U.S. Department of Labor and State agencies administering Workers Compensation program, and the Insurance Services Office (ISO).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Insurance Match Agreement	22	1	0.50	11
Insurance Match File	22	0.50	0.50	132

Estimated Total Annual Burden Hours: 143.

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:* 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, *E-mail:* OIRA_SUBMISSION@OMB.eop.gov,

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0429]

Draft Guidances for Industry and Food and Drug Administration Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues; and Interpretation of the Term "Chemical Action" in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two related draft

guidances for industry and FDA staff entitled "Draft Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues" and "Draft Guidance for Industry and FDA Staff: Interpretation of the Term 'Chemical Action' in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act." These draft guidances provide the Agency's current thinking on approaches for classifying products as drugs and devices, certain additional product classification issues, and the interpretation of the term "chemical action" under the FD&C Act.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft guidances before it begins work on the final versions of these guidances, submit either electronic or written comments on the draft guidances by September 19, 2011.

ADDRESSES: Submit written requests for single copies of these draft guidances to the Office of Combination Products, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive

label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidances 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.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of two draft guidances for industry and FDA staff entitled “Draft Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues” (Draft Classification Guidance) and “Draft Guidance for Industry and FDA Staff: Interpretation of the Term ‘Chemical Action’ in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act” (Draft Chemical Action Guidance). These draft guidances provide the Agency’s current thinking on approaches for classifying products as drugs and devices, certain additional product classification issues, and the interpretation of the term “chemical action” under section 201(h).

FDA determines whether to classify a product as a drug or device based on the statutory definitions for these terms set forth in sections 201(g) and 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)(21 U.S.C. 321(g) and 321(h)), respectively, as applied to the scientific data concerning the product that are available to FDA at the time the classification determination is made.

The Draft Classification Guidance addresses three topics: (1) It explains how to obtain a formal classification determination for a medical product; (2) it presents the Agency’s current thinking on the interpretation of the statutory definitions of device and drug, other than the term “chemical action” in the definition of device at section 201(h), which is addressed in the Draft Chemical Action Guidance, as discussed in the following paragraphs; and (3) it presents the Agency’s current thinking on the status of published intercenter jurisdictional agreements, current regulations establishing classifications, and classifications the Agency has otherwise previously made for specific products.

The definition of device at section 201(h) states, in part, that a device “does not achieve its primary intended purposes through *chemical action* within or on the body of man or other animals.” The term “chemical action” in this phrase is often important in determining whether a product meets the definition of device at section 201(h). The Draft Chemical Action Guidance presents the Agency’s current thinking on the interpretation of the term “chemical action” for purposes of this definition. The Draft Chemical Action Guidance states that a product exhibits chemical action if: “through either chemical reaction or intermolecular forces or both, the product mediates a bodily response at the cellular or molecular level, or combines with or modifies an entity so as to alter that entity’s interaction with the body of man or other animals.”

The Agency welcomes all comments on the Draft Classification Guidance and the Draft Chemical Action Guidance. In particular, we request comment on the following two topics:

1. Application of the approaches articulated in these two draft guidances to specific groups of products.

We seek input on how groups of products would be classified under these approaches and the regulatory implications of those classifications. While we welcome more general input on the approaches announced, we are seeking particular comments regarding the application of these approaches to specific products or groups of products. We note that questions concerning whether to classify a product as a drug or device have most frequently arisen with respect to products consisting of gels, liquids, semi-liquids, or powders that come into contact with the body.

We also seek input on whether or how to clarify or modify any elements or terms of the approaches presented. For example, the approach for whether a product exhibits chemical action quoted previously from the Draft Chemical Action Guidance includes the phrase “mediates a bodily response at the cellular or molecular level.” We welcome input on this phrase or any other aspect of this approach.

2. Relationship between these classification approaches and prior classification determinations.

As noted previously, the Draft Classification Guidance discusses the Agency’s current thinking on the status of the current published intercenter jurisdictional agreements, regulations establishing classifications, and other classifications of specific products (e.g., via marketing authorizations or requests for designation). We seek comment on

the concepts presented in this section of the Draft Classification Guidance. For example, we welcome comment on procedures for determining whether to change current product classifications and, if so, how to implement those changes appropriately.

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the Agency’s current thinking on classification of products as drugs and devices, certain additional product classification issues, and the interpretation of the term “chemical action” under section 201(h). They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The draft guidance on classification of products as drugs or devices refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 3 have been approved under OMB control number 0910-0523.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding these documents. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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