DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

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 insurer may choose to conduct the data comparison 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 then compare that information with information pertaining to individuals owing past-due support.

Under the second method, OCSE will send 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 then send the information resulting from the comparison to OCSE.

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

This information collection is authorized by: (1) 42 U.S.C. 652(a)(9) which requires the federal Office of Child Support Enforcement (OCSE) to operate the FPLS established by 42 U.S.C. 653(a)(1); 42 U.S.C. 652(l) (to be redesignated (m)) which authorizes OCSE, through the FPLS to compare information concerning individuals owing past-due support with information maintained by insurers (or their agents) concerning insurance claims, settlements, awards, and payments, and to furnish information resulting from the data matches to the state child support agencies responsible for collecting child support from the individuals.

Respondents: Insurers or their agents, including the U.S. Department of Labor and state agencies administering workers' compensation programs, 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 File	22	12	0.50	132

Estimated Total Annual Burden Hours: 132.

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email address: *infocollection@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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–05195 Filed 3–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to the Federal Food, Drug, and Cosmetic Act

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 10, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0679. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–0679)—Extension

In the **Federal Register** of June 8, 2011 (76 FR 33309), FDA announced the availability of a guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' The guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) (21 U.S.C. 355(b)(2) or 21 U.S.C. 355(j)) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending abbreviated new drug application (ANDA) or a section 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and section 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112–144, 126 Stat. 993). Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened FDA's deadline from 180 days to 150 days for responding to petitions subject to section 505(q) of the FD&C Act. Second, it expanded the scope of section 505(q) of the FD&C Act to include certain petitions concerning applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, we are now including submissions pertaining to biosimilar biological product applications in the information collection burden estimates in this document.

Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of agency action include a verification to be accepted for review by FDA. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) of the FD&C Act apply to a particular citizen petition or petition for stay of agency action. The guidance states that one of the criteria for a citizen petition or petition for stay of agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or section 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or section 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or section 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or section 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act and the petitioner would like FDA to review the citizen petition or petition for stay of agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB control number 0910–0183). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b) (21 CFR 10.30(b))); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b) (21 CFR 10.35(b))); and (5) the submission of written comments on a filed petition for administrative stay of action (§ 10.35(c)). This information collection includes citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described previously in this document, which are subject to section 505(q) of the FD&C Act and described in the guidance.

We are requesting OMB approval for the following collection of information submitted to FDA under section 505(q) of the FD&C Act and the guidance:

1. The certification required under section 505(q)(1)(H) of the FD&C Act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, section 505(b)(2) application, or biosimilar biological product application. Although the submission of a certification for citizen petitions is approved under OMB control number 0910–0183, the certification would be broadened under section 505(q) of the FD&C Act and the guidance.

2. The certification required under section 505(q)(1)(H) of the FD&C Act for petitions for stay of agency action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, section 505(b)(2) application, or biosimilar biological product application.

3. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to citizen petitions.

4. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to petitions for stay of agency action.

5. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.

6. Supplements to petitions for stay of agency action.

7. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of agency action.

8. The letter submitted by a petitioner withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA, section 505(b)(2) application, or biosimilar biological product application is necessary based on a petition subject to section 505(q), the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB control number 0910–0001.

In the **Federal Register** of October 1, 2013 (78 FR 60288), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received that pertained to the information collection analysis.

Based on FDA's knowledge of citizen petitions and petitions for stay of agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the Agency's familiarity with the time needed to prepare a supplement, a certification, and a verification, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification for citizen petitions (505(q)(1)(H))	26	1.15	32	0.5 (30 min.)	16
Certification for petitions for stay of agency action (505(q)(1)(H))	1	1	1	0.5 (30 min.)	0.5
Verification for comments to citizen petitions (505(q)(1)(I))	9	1.33	12	0.5 (30 min.)	6
Verification for comments to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5 (30 min.)	0.5
Verification for supplements to citizen petitions (505(q)(1)(I))	7	1.43	10	0.5 (30 min.)	5
Supplements to petitions for stay of agency action	1	1	1	6	6
Verification for supplements to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5 (30 min.)	0.5
Letter withdrawing a petition for stay of agency action	1	1	1	0.5 (30 min.)	0.5
Total Hours		35			

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

Dated: March 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05190 Filed 3–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0264]

Draft Guidance for Industry on Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment; 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 ''Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME).

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 comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 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.

FOR FURTHER INFORMATION CONTACT: Janet Maynard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3185, Silver Spring, MD 20993–0002, 301–796–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of CFS/ME.

Currently, there are no approved therapies indicated to treat CFS/ME. The lack of approved therapies indicated for the treatment of CFS/ME represents a public health concern. To foster drug development in CFS/ME, this draft guidance outlines the following key issues in drug development in CFS/ME:

- The case definitions or criteria for CFS/ME that could be used to define a patient population in the context of drug development