DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0085]

Submission for OMB Review; Provision of Services in Intergovernmental IV–D; Federally Approved Forms

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: This is a revision to an existing data collection which expires December 31, 2019. This data collection consists of 13 intergovernmental forms used by States and other entities to process intergovernmental child support cases. This request is for minor revisions to the approved forms.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Public Law 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 forms mandated by Federal law. 45 CFR 303.7(a)(4) also requires child support programs to use federally-approved forms in intergovernmental IV–D cases unless a country has provided alternative forms.

Proposed changes to the forms include updates for clarification and consistency to the instructions on all of the forms. Additional changes include:

- On the Child Support Enforcement Transmittal #3—Request for Assistance/Discovery, the addition of a new case processing action to facilitate payment processing for a direct Income Withholding Order, and the revision of the payment forwarding action.
- On the Declaration in Support of Establishing Parentage, the revision of the declaration signature section to make it consistent with the General Testimony and more flexible for cases involved children in foster care.

Respondents: State agencies administering a child support 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—Initial Request	54	18,246	0.17	167,498
Transmittal #1—Initial Request Acknowledgement *	54	18,246	0.05	49,264
Transmittal #2—Subsequent Action	54	13,685	0.08	59,119
Transmittal #3—Request for Assistance/Discovery	54	2,737	0.08	11,824
Uniform Support Petition	54	7,298	0.05	19,705
General Testimony	54	7,298	0.33	130,050
Declaration in Support of Establishing Parentage	54	2,737	0.15	22,170
Child Support Locate Request	54	182	0.05	491
Notice of Determination of Controlling Order	54	2	0.25	27
Letter of Transmittal Requesting Registration	54	10,948	0.08	47,295
Personal Information Form For UIFSA § 311 *	54	7,298	0.05	19,705
Child Support Agency Confidential Information Form *	54	21,895	0.05	59,117
Request for Change of Support Payment Location Pursuant to UIFSA 319(b) *	54	91	0.05	246

Estimated Total Annual Burden Hours: 586,511.

Authority: 45 CFR 303.7.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–23300 Filed 10–24–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4611]

Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of Compliance Policy Guide Sec. 400.400 (CPG 400.400) entitled ''Conditions Under Which Homeopathic Drugs May be Marketed,'' which was issued in 1988.

DATES: The withdrawal is applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA is withdrawing CPG 400.400, entitled ''Conditions Under Which Homeopathic Drugs May be Marketed,'' which was issued in 1988. CPG 400.400 described an enforcement policy regarding homeopathic drug products.

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), before any ''new drug'' is marketed, it must be the subject of an approved application filed pursuant to section 505(b) or section 505(j) of the FD&C Act. The requirements in section 505 of the FD&C Act apply to biological products regulated under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262); however, as stated in section 351(j) of the PHS Act, a biological product with an approved license under section 351(a) of the PHS Act is not required to have an approved application under section 505 of the FD&C Act. Accordingly, absent a determination that a homeopathic drug product is not a ''new drug'' under section 201(p) of the FD&C Act (21 U.S.C. 321(p)), all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act. There are currently no homeopathic drug products approved by FDA.

Since the issuance of CPG 400.400, the Agency has encountered multiple situations in which homeopathic drug products posed a significant risk to patients. There is a broad misconception that all homeopathic products are highly diluted and generally composed of ''natural'' ingredients, and that they are therefore incapable of causing harm. However, as with all drugs, the safety of homeopathic drugs depends upon many factors, such as the product's intended use, dosage form, frequency of use, manufacturing quality, intended patient population, and the quantity and combination of ingredients. CPG 400.400 does not directly address all these important considerations.

For example, FDA has encountered situations in which homeopathic products either caused or could have caused significant harm, even though the products, as labeled, appeared to meet the conditions described in CPG 400.400. In 2016, FDA's search of the FDA Adverse Event Reporting System database identified 99 cases of adverse events consistent with belladonna toxicity, including reports of infant deaths and seizures, possibly related to teething products. Multiple homeopathic drug products were identified as associated with this safety concern. Further investigation revealed that the poisonous belladonna alkaloids in some of the products far exceeded the labeled amounts, raising a serious safety concern. As another example, by 2009, FDA had received more than 130 reports of anosmia (loss of the sense of smell) associated with the use of Zicam homeopathic intranasal zinc products. FDA determined that if the products were used as labeled, a user would receive significant daily intranasal exposure to zinc, raising a serious safety concern. These are only two examples among many. FDA has also, for example, documented many serious violations of current good manufacturing practice (CGMP) requirements by manufacturers of homeopathic drug products, raising significant concerns about the safety of the products made with inadequate process controls.

The homeopathic drug industry has grown significantly since FDA issued CPG 400.400 in 1988. According to the National Health Interview Survey, conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, between 2007 and 2012 the use of homeopathic products increased by approximately 15 percent in U.S. adults. This growth, and the increased population exposure that it apparently represents, has contributed to FDA's enhanced focus on the safety of homeopathic drugs in recent years and the evaluation of the CPG, which was issued over three decades ago.

In light of the growth of the industry and passage of time since the issuance of CPG 400.400, FDA announced on March 27, 2015, that it was evaluating its regulatory framework for homeopathic drug products. In April 2015, FDA held a public hearing to obtain information and comments from stakeholders about the current use of homeopathic drug products, as well as the Agency's regulatory framework for such products (Docket No. FDA–2015–N–0540; available at *https://www.regulations.gov/docket?D=FDA-2015-N-0540*). FDA sought broad public input on its enforcement policies related to homeopathic drug products to better promote and protect the public health. On December 18, 2017, FDA issued a draft guidance entitled ''Drug Products Labeled as Homeopathic; Guidance for FDA Staff and Industry.'' The draft guidance detailed a risk-based enforcement policy, prioritizing enforcement and regulatory actions for certain categories of homeopathic products that potentially pose higher risk to public health.

In response to comments received, we have revised the draft guidance and are announcing the reissue of it elsewhere in this issue of the **Federal Register** to enable the public to review and comment before it is finalized. In particular, we have added a definition of ''homeopathic drug product'' for purposes of the guidance, added an additional explanation of some of the safety issues that contributed to the development of the draft guidance, and clarified the intent to use risk-based factors to prioritize enforcement and regulatory actions involving homeopathic products that are marketed without required FDA approval. In addition, the revised draft guidance removes the statement that the Agency will withdraw the CPG simultaneous with the issuance of the final guidance.

As a result of the Agency's ongoing evaluation of its regulatory framework, including consideration of the public input received on this issue and the recent growth of safety concerns associated with homeopathic drug products, FDA believes that it is appropriate to withdraw CPG 400.400 at this time, rather than waiting for the issuance of the final guidance. Because CPG 400.400 is inconsistent with the Agency's risk-based approach to enforcement generally, it does not accurately reflect the Agency's current thinking. When the draft guidance is finalized, it will specify the categories of products that the Agency intends to prioritize for enforcement. In the interim, before the draft guidance is finalized, FDA intends to apply its general approach to prioritizing regulatory and enforcement action, which involves risk-based prioritization in light of all the facts of a given circumstance. Risk-based enforcement best reflects FDA's public health priorities.

We note that withdrawing the CPG does not represent a change in the legal obligations that apply to homeopathic drugs under the statutes FDA administers. The definition of a ''drug'' under section 201(g)(1)(A) through (C) of the FD&C Act includes: (1) Articles recognized in the official United States Pharmacopoeia or the official Homoeopathic Pharmacopoeia of the United States; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals. As such, homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drug products from any of the requirements in the FD&C Act, including those related to approval, adulteration, and misbranding.

Generally, a drug, including a homeopathic drug, is considered a ''new drug'' if it is not generally recognized as safe and effective by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling (section 201(p) of the FD&C Act). CPG 400.400 did not, and legally could not, provide a path for legal marketing of unapproved new drugs, including those that are homeopathic. Rather, the CPG merely described an enforcement policy regarding homeopathic drug products. The Agency does not have authority to exempt a product or class of products that are new drugs under the FD&C Act from the new drug approval requirements of the FD&C Act. (See *Cutler* v. *Kennedy,* 475 F. Supp. 838, 856 (D.D.C. 1979); *Hoffman-LaRoche* v. *Weinberger,* 425 F. Supp. 890, 892–894 (D.D.C. 1975). See also *Util. Air Regulatory Grp.* v. *EPA,* 573 U.S. 302, 327 (2014) (''An agency confronting resource constraints may change its own conduct, but it cannot change the law.'')).

The Agency's interest in its general risk-based enforcement approach also justifies withdrawing an outdated policy that does not reflect that approach. Additionally, withdrawal of the CPG is appropriate given the recent growth of safety concerns associated with homeopathic drug products—including concerns regarding products associated with serious adverse events and otherwise presenting significant safety risks and serious violations of CGMP requirements—and the increasing number of consumer exposures due to the continued expansion of the homeopathic industry since issuance of the CPG.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23334 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6580]

Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for FDA staff and industry entitled ''Drug Products Labeled as Homeopathic.'' The revised draft guidance, like the original version, describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval that potentially pose higher risk to public health. In response to comments received, we have revised the draft guidance and are reissuing it in draft form to enable the public to review and comment before it is finalized.

DATES: Submit either electronic or written comments on the draft guidance by January 23, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6580 for ''Drug Products Labeled as Homeopathic.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building,