

comprehensive development process, AIDD published a notice in the **Federal Register** on February 18, 2016 seeking comments on a new funding formula (81 FR 8204). AIDD has reviewed the comments submitted and is moving forward with the proposed formula. AIDD believes that this formula is clear, concise, transparent, and consistent with Congress' intent to provide funds to States based on greatest need. For the P&A program, in response to the comments received, AIDD will adopt this new formula over a three year period.

For complete details on methodology and development of the new formula please see the **Federal Register**, February 18, 2016, Vol 81, Number 32, Pages 8204–8205.

New Formula

Beginning in FY 2017, AIDD will use a new formula to distribute funds to SCDD and P&A programs after meeting statutory minimums and hold-harmless requirements for the SCDD. Funding will be allocated to States and Territories based on the following criteria:

1. *State/Territory Population (30%)*: Based on July Census figures released in August of each year.

2. *Need for services (30%)*: Based on a 1.58 percent prevalence rate for developmental disabilities in each State and Territory from the HHS National Health Interview Survey on Disability (NHIS–D).

3. *Financial need (40%)*: Based on a combination of poverty (20%) and seasonally adjusted unemployment rates (20%) from July of each calendar year.

New Formula Phase-In

In their comments to AIDD, numerous P&A programs requested to phase in the new formula as a way of offsetting losses some grantees would experience if AIDD were to begin using the new formula immediately in FY 2017. AIDD concurs with this requested approach, and the new formula will be phased in for the P&A programs only with funds allotted in the following manner:

FY 2017: 75 percent previous formula and 25 percent new formula

FY 2018: 50 percent previous formula and 50 percent new formula

FY 2019: 100 percent new formula

The new formula will be in full effect for the SCDD programs on October 1, 2016. SCDDs will likely not experience significant fluctuations in their annual allotment due to that program's hold-harmless requirement.

Response to Public Comments

General

AIDD received 75 comments related to the new formula including 39 comments from SCDDs and 18 from P&As. AIDD also received 18 comments from other entities including non-profits and State agencies. Comments were received on each of the three required formula factors and weighting of the factors. Comments on the new formula were generally favorable and supportive. Commenters acknowledged that the current formula is more than 35 years old and uses data sources that do not adequately take into account the needs of people with developmental disabilities. Generally, they found the new formula to be more transparent and easier to understand. Comments also reinforced the need for the new formula in order to ease the administrative burden on ACL. Commenters pointed out that the previous formula used the per capita income rate which was an inadequate way to measure financial need and AIDD concurs with this comment. Several commenters stated that the current minimum allotments are inadequate; however these minimum allotments are set in statute and therefore not subject to change by AIDD.

Population

Some commenters requested that population have a higher weight in the formula. AIDD declined to raise the weighting as doing so could cause larger swings in the formula year-to-year and thereby make it more difficult for States to plan for their operating needs. Some commenters asked for the population of people with developmental disabilities to be considered rather than the total population. However, the DD Act requires that the entire State population must be taken into consideration.

Need for Services

As the formula workgroup and AIDD determined, the most clear and concise way to determine the need for services was to use the most current federal data for prevalence of people with developmental disabilities. Some commenters asked that AIDD use the Centers for Disease Control (CDC) prevalence rates for people with developmental disabilities, however, CDC's definition of developmental disabilities does not match AIDD's statutory definition.

Several commenters asked for different data to be used to determine the need for services in each State and Territory. There were varied opinions and suggestions, but none were clearly

stronger than the sources proposed by AIDD.

Commenters also asked for the use of prevalence rates by State. That data is not currently available. AIDD is working with its federal partners to identify future opportunities to better understand the prevalence of developmental disabilities.

Financial Need

AIDD and the formula workgroup weighted financial need at 40 percent, with 20 percent based on State/Territory poverty levels and 20 percent based on seasonally adjusted unemployment data from July of each year. The workgroup felt that these measures were the best economic indicators to measure a State's financial need.

Several commenters asked for additional measures such as cost of living adjustments, workforce participation rates, and supplemental measures of poverty. HHS data experts stated that these data were not as reliable as the ones proposed and that the use of any of these data, including workforce participation rates, would not make a significant difference in the distribution of funds. Further, use of several of the proposed data would make the formula more complicated. Other commenters stated the need to use different data sources but did not give alternatives as was requested in the request for public comments. Therefore, AIDD concluded that there was no compelling reason to change data used for financial need.

Dated: May 5, 2016.

Jennifer Johnson,

Deputy Director, Administration on Intellectual and Developmental Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0730]

Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for data needed to evaluate requests for Threshold of Regulation Exemptions for Substances Used in Food-Contact Articles.

DATES: Submit either electronic or written comments on the collection of information by July 11, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2013-N-0730 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver

Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39 (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct

food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4)

data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.*, food packaging and food processing equipment) or of the articles themselves.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR 170.39	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles	7	1	7	48	336

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

In compiling these estimates, we consulted our records of the number of regulation exemption requests received in the past three years. The annual hours per response reporting estimate of 48 hours is based on information received from representatives of the food packaging and processing industries and Agency records.

We estimate that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of FD&C Act (OMB control number 0910-0495) in that the use of a substance exempted by FDA is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (*e.g.*, use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and we would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date

list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: May 5, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0450]

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of abbreviated new animal drug applications.

DATES: Submit either electronic or written comments on the collection of information by July 11, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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