DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: ACF Program Instruction—Children’s Justice Act (OMB #0970–0425)

AGENCY: Children’s Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Children’s Justice Act Program Instruction (OMB #0970–0425, expiration 4/30/2020). There are no changes requested to the form.

DATES: Comments due within 60 days of publication. In compliance with the requirements of Section 3506(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.

ADDRESS: Copies of the proposed collection of information can be obtained and comments may be forwarded 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 (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Program Instruction, prepared in response to the enactment of the Children’s Justice Act (CJA), Title II of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the states and territories to accomplish the purposes of assisting states in developing, establishing, and operating programs designed to improve: (1) The assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the family’s; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at sections 107(b) and 107(d), and pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate, and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total number of respondents</th>
<th>Annual number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Annual burden hours</th>
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</thead>
<tbody>
<tr>
<td>Application and Annual Report</td>
<td>52</td>
<td>1</td>
<td>60</td>
<td>3,120</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 3,120.

Comments: 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.

Authority: 42 U.S.C. 5106c Sec. 107(b)(4) and 42 U.S.C. 5106 Sec. 107(B)(5).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–00739 Filed 1–16–20; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2495]

Request for Nominations for Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health. Nominations will be accepted for current and upcoming vacancies effective with this notice.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before March 17, 2020, will be given first consideration for membership on TEPRSSC. Nominations received after March 17, 2020, will be considered for nomination to the committee as later vacancies occur.

ADDRESS: All nominations for membership should be sent electronically by accessing FDA’s Advisory Committee Membership Nomination Portal at https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA’s website at https://www.fda.gov/AdvisoryCommittees/default.htm.
FOR FURTHER INFORMATION CONTACT: Patricio G. Garcia, Division of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–796–6875, email: Patricio.Garcia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on TEPRSSC that include three general public representatives.

I. General Description of the Committee’s Duties

The committee provides advice and consultation to the Commissioner of Food and Drugs (Commissioner) on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

II. Criteria for Voting Members

The committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the committee by appropriate action prior to its expiration.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see ADDRESSES). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, financial research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2020–00733 Filed 1–16–20; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 February 18, 2020.

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 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRAsStaff@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.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

OMB Control Number 0910–0338—Extension

Under section 351 of the Public Health Services Act (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) (21 CFR 601.2(a)) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65. The estimate for these regulations is...