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. 2014–15927 Filed 7–8–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Methodology for Determining Whether an Increase in a State's Child Poverty Rate is the Result of the TANF Program

OMB No.: 0970–0186

Description

In accordance with Section 413(i) of the Social Security Act and 45 CFR part 284, the Department of Health and Human Services (HHS) intends to extend without change the following information collection requirements. For instances when Census Bureau data show that a States child poverty rate increased by 5 percent or more from one year to the next, a State may submit independent estimates of its child poverty rate. If HHS determines that the States independent estimates are not more reliable than the Census Bureau estimates, HHS will require the State to submit an assessment of the impact of the TANF program(s) in the State on the child poverty rate. If HHS determines from the assessment and other information that the child poverty rate in the State increased as a result of the TANF program(s) in the State, HHS will then require the State to submit a corrective action plan.

Respondents

The respondents are the 50 States and the District of Columbia. When reliable Census Bureau data become available for the Territories, additional respondents might include Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Optional Submission of Data on Child Poverty from an Independent Source	51	1	8	408
Assessment of the Impact of TANF on the Increase in Child Poverty	51	1	120	6,120
Corrective Action Plan	51	1	160	8,160

Estimated Total Annual Burden Hours: 14,688.

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. 2014–15944 Filed 7–8–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0144]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

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 requirements for certain FDA applications or submissions to be accompanied by a certification, Form FDA 3674, to ensure all applicable statutory requirements have been met.

DATES: Submit either electronic or written comments on the collection of information by September 8, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 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.

Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)—(OMB Control Number 0910–0616)—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and is already approved by OMB. The OMB control numbers and expiration dates for submitting FDA 3674 under the following parts are: 21 CFR parts 312 and 314 (human drugs) are 0910–0014, expiring April 30, 2015, and 0910–0001, expiring September 30, 2014; 21 CFR parts 312 and 601 (biological products) are 0910–0014 and 0910–0338, expiring January 31, 2017; 21 CFR parts 807 and 814 (devices) are 0910–0120, expiring January 31, 2017, and 0910–0231, expiring January 31, 2017.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) amended the PHS Act by adding section 402(j). The provisions require additional information to be submitted to the clinical trials data bank, *http://www.clinicaltrials.gov/* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**) previously established by the National Institutes of Health/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties.

In January 2009, FDA issued ''Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff—Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance With Section 402(j) of The Public Health Service Act, Added By Title VIII of the Food and Drug Administration Amendments Act of 2007'' available at *http://www.fda.gov/regulatoryInformation/guidances/ucm125335.htm*. This guidance identified the applications and submissions that FDA considered should be accompanied by the certification form, Form FDA 3674. The applications and submissions noted in the guidance are reflected in the burden analysis.

Investigational New Drug Applications

FDA's Center for Drug Evaluation and Research (CDER) received 1,564 investigational new drug applications (INDs) and 14,328 clinical protocol IND amendments in calendar year (CY) 2013. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 451 new INDs and 492 clinical protocol IND amendments in CY 2013. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future. The estimated total number of submissions (new INDs and new protocol submissions) subject to

mandatory certification requirements under section 402(j)(5)(B) of the PHS Act, is 15,892 for CDER plus 943 for CBER, or 16,835 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that approximately 15 minutes on average would be needed per response for certifications which accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained a NCT number from *http://www.clinicaltrials.gov/* prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions

In CY 2013, CDER and CBER received 226 new drug applications (NDA)/biologics license applications (BLA)/resubmissions and 932 NDA/BLA amendments for which certifications are needed. CDER and CBER received 198 efficacy supplements/resubmissions to previously approved NDAs/BLAs in CY 2013. CDER and CBER anticipate that new drug/biologic applications/resubmissions and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received a total of 530 new applications for premarket approvals (PMA), 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments in CY 2013. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

FDA's Office of Generic Drugs (OGD) received 1,001 abbreviated new drug applications (ANDAs) in 2013. OGD received 989 bioequivalence amendments/supplements in 2013. OGD anticipates that application, amendment, and supplement submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER						
New Applications (IND)	1,564		1	1,546	0.25 (15 minutes)	387
Clinical Protocol Amendments (IND).	14,328		1	14,328	0.25 (15 minutes)	3,582
New Marketing Applications/R Resubmissions (NDA/BLA).		191	1	191	0.75 (45 minutes)	143
Clinical Amendments to Marketing Applications.		932	1	932	0.75 (45 minutes)	699
Efficacy Supplements/Resubmissions.		173	1	173	0.75 (45 minutes)	130
CBER						
New Applications (IND)	451		1	451	0.25 (15 minutes)	113
Clinical Protocol Amendments (IND).	492		1	492	0.25 (15 minutes)	123
New Marketing Applications/Resubmissions (NDA/BLA).		35	1	35	0.75 (45 minutes)	26
Clinical Amendments to Marketing Applications.		0	1	0	0.75 (45 minutes)	1
Efficacy Supplements/Resubmissions (BLA only).		25	1	25	0.75 (45 minutes)	19
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data).		530	1	530	0.75 (45 minutes)	398
OGD						
Original Applications		1,001	1	1,001	0.75 (45 minutes)	751
BE Supplements/Amendments		989	1	989	0.75 (45 minutes)	742

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

FDA center activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total						7,114

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

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15992 Filed 7–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0852]

Draft Guidance for Industry: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products'' dated July 2014. The draft guidance document provides sponsors of virus or bacteria-based gene therapy products (VBGT products) and oncolytic viruses or bacteria (oncolytic products) with recommendations on how to conduct shedding studies during preclinical and clinical development.

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 November 19, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products'' dated July 2014. The draft guidance document provides sponsors of oncolytic and VBGT products with recommendations on how to conduct shedding studies during preclinical and clinical development. Oncolytic and VBGT products are derived from infectious viruses or bacteria. In general, these product-based viruses and bacteria are not as infectious or as virulent as the parent strain of virus or bacterium. Nonetheless, FDA is issuing this guidance because the possibility that infectious product-based viruses and bacteria may be shed by a patient raises safety concerns related to the risk of transmission to untreated individuals. To understand the risk associated with product shedding, sponsors should collect data in the target patient population in clinical trials before licensure.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance 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 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0308; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.*

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15991 Filed 7–8–14; 8:45 am]

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