Occasionally; *Affected Public:* Private sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 1,796,502; *Total Annual Responses:* 1,796,502; *Total Annual Hours:* 559,713. (For policy questions regarding this collection contact Kia Sidbury at 410–786–7816. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Subpart D—Private Contracts and Supporting Regulations Contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455. *Use:* Section 4507 of Balancing Budget Act (BBA) 1997 amended section 1802 of the Social Security Act to permit certain physicians and practitioners to opt-out of Medicare and to provide (through private contracts) services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the supporting regulations counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits. Physicians and/or practitioners use these information collection requirements to comply with the law. In addition, Medicare carriers use this information to determine if benefits should be paid or continued. *Form Number:* CMS–R–234 (OCN 0938–0730); *Frequency:* Biennially; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 26,820. *Total Annual Responses:* 26,820. *Total Annual Hours:* 7,197. (For policy questions regarding this collection contact Fred Grabau at 410–786–0206. For all other issues call 410–786–1326.)

Dated: *June 4, 2013.*

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–13577 Filed 6–6–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Guidance for Tribal TANF.

OMB No.: 0970–0157.

Description

42 U.S.C. 612 (Section 412 of the Social Security Act) requires each Indian Tribe that elects to administer and operate a Temporary Assistance for Needy Families (TANF) program to submit a TANF Tribal Plan. The TANF Tribal Plan is a mandatory statement submitted to the Secretary by the Indian Tribe, which consists of an outline of how the Indian Tribes TANF program will be administered and operated. It is used by the Secretary to determine whether the plan is approvable and to determine that the Indian Tribe is eligible to receive a TANF assistance grant. It is also made available to the public.

Respondents

Indian Tribes applying to operate a TANF program.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for State Data Needed to Determine the Amount of a Tribal Family Assistance Grant	23	1	68	1564

Estimated Total Annual Burden Hours: 1,564.

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–13536 Filed 6–6–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0179]

Guidance for Industry and Food and Drug Administration Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products,'' dated June 2013. The final guidance document provides technical and scientific

information for sponsors to consider in developing information to support a marketing application for a pen, jet, or related injector device intended for use with drugs or biological products. The marketing application would typically be a premarket notification submission (510(k)) or a premarket approval (PMA) application for the injector alone. For a combination product that includes the injector, the marketing application would typically be a new drug application (NDA) or a biological licensing application (BLA). The guidance announced in this notice finalizes the draft guidance of the same title dated April 2009 and published under Docket No. FDA–2009–D–0179.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301–796–8930. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Patricia Y. Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products'' dated June 2013. FDA is providing this final guidance document to assist industry in developing technical and scientific information to support a marketing application for a pen, jet, or related injector device. The marketing application would typically be a 510(k) or a PMA application for the injector alone. For a combination product that includes the injector, the marketing application would typically be an NDA or a BLA. For purposes of this guidance, the term injector includes, but is not limited to, jet injectors, pen injectors, piston syringes, needle-free injectors, mechanically operated injectors, and injectors with computerized or electronic elements.

In the **Federal Register** on April 27, 2009, (74 FR 19094), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The final guidance is largely similar to the draft guidance. The significant changes to the guidance include: Additional information to clarify the bases for the technical and scientific recommendations for general use injectors, injectors intended for a class/family of drugs or biological products, injectors intended for a sponsor's product line, and injectors for use with a specific drug or biological product. The guidance provides additional information to assist developers in considering the relevance of already approved drug or biological product labeling in the development of injectors intended for general use or for use with a class/family or product line, which should assist in developing labeling for the injectors. The document provides links to other Agency documents published since the April 2009 draft guidance. Also, the document contains editorial and terminology changes to improve clarity and readability. The guidance announced in this notice finalizes the draft guidance dated April 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review and have been approved 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 807 have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Comments

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 guidance at either *http://www.fda.gov/CombinationProducts/default.htm* or *http://www.regulations.gov.*

Dated: May 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13484 Filed 6–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0602]

Electronic Submission of Tobacco Product Applications and Other Information; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing a 1-day workshop to obtain public input on topics related to the potential electronic submission of tobacco product applications and other information. This workshop will focus on the technical aspects of electronic submissions, including potential standards for content, format, and structure. The input from the public workshop may assist the Agency in the potential development and implementation of an electronic submission standard for CTP. FDA is also opening a public docket to receive comments on this topic.

Date and Time: The public workshop will be held on July 18, 2013, from 9