sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead can also be sent by email to *wliberante@omb.eop.gov.*

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2019–00904 Filed 2–1–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0215]

Submission for OMB Review; Comment Request

Title: Tribal TANF Data Report, TANF Annual Report, and Reasonable Cause/Corrective Action Documentation Process–Final

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act as amended by Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA)), mandates that federally recognized Indian Tribes with an approved Tribal TANF program collect and submit to the Secretary of the Department of Health and Human Services data on the recipients served by the Tribes' programs. This information includes both aggregated and disaggregated data on case characteristics and individual characteristics. In addition, Tribes that are subject to a penalty are allowed to provide reasonable cause justifications as to why a penalty should not be imposed or may develop and implement corrective compliance procedures to eliminate the source of the penalty. Finally, there is an annual report, which requires the Tribes to describe program characteristics. All of the above requirements are currently approved by OMB and the Administration for Children and Families is simply proposing to extend them without any changes.

Respondents: Federally recognized Indian tribes

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
FINAL tribal TANF report	74	4	451	133,496
Tribal TANF Annual Report	74	1	40	2,960
Tribal TANF reasonable cause/corrective	74	1	60	4,440

Estimated Total Annual Burden Hours: 140,896.

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, 330 C Street SW, Washington, DC 20201. Attention 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–00808 Filed 2–1–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Prevention Services Data Collection.

OMB No.: 0970–NEW.

Description: Section 471(e)(4)(E) of the Social Security Act (the Act) (42 U.S.C. 671) as amended by Public Law 115–123 requires state and tribal child welfare agencies to collect and report to the Administration for Children and Families (ACF) information on children receiving prevention and family services and programs. States and tribes must report:

- The specific services or programs provided,
- The total expenditures for each of the services or programs provided,
- The duration of the services or programs provided, and
- If the child was identified in a prevention plan as a candidate for foster care:
  - The child's placement status at the beginning, and at the end, of the 12 month period that begins on the date the child was identified as a candidate for foster care in a prevention plan; and
  - whether the child entered foster care during the initial 12 month period and during the subsequent 12 month period.

It is anticipated that half or less of the tribes and states will choose to provide these prevention services in the first years of the program availability, but that number will increase over time.

The data collected will inform federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data will provide information about the use and availability of prevention services to children to prevent the need for foster care placement. The data will contain personally identifiable information (date of birth and race/ethnicity).

Respondents: State and tribal child welfare agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Prevention Services Data Collection	20	1	31	620

Estimated Total Annual Burden Hours: 620.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), 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, 330 C Street SW, Washington, DC 20201. 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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–00895 Filed 2–1–19; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–P–1877 and FDA–2018–P–3730]

Determination That ESBRIET (Pirfenidone) Film Coated Tablets, 534 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ESBRIET (pirfenidone), film coated tablets, 534 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for pirfenidone, film coated tablets, 534 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 301–796–6650.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ESBRIET (pirfenidone), film coated tablets, 534 mg, is the subject of NDA 208780, held by Genentech, Inc., and initially approved on January 11, 2017. ESBRIET is indicated for the treatment of idiopathic pulmonary fibrosis. ESBRIET (pirfenidone), film coated tablets, 534 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Laurus Labs Ltd. submitted a citizen petition dated May 14, 2018 (Docket No. FDA–2018–P–1877), and Aziant Drug Research Solutions Pvt. Ltd. Submitted a citizen petition dated October 1, 2018 (FDA–2018–P–3730), under 21 CFR 10.30, requesting that the Agency determine whether ESBRIET (pirfenidone), film coated tablets, 534 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ESBRIET (pirfenidone), film coated tablets, 534 mg, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ESBRIET (pirfenidone), film coated tablets, 534 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ESBRIET (pirfenidone), film coated tablets, 534 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug