DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; National Directory of New Hires

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement; Administration for Children and Families (ACF) is requesting a three-year extension of the National Directory of New Hires (OMB #0970–0166, expiration 7/31/2019). The NDNH Guide for Data Submission/Record Specifications and the Multistate Employer Registration form underwent minor revisions.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: 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.

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

SUPPLEMENTARY INFORMATION:

Description: The federal Office of Child Support Enforcement operates the National Directory of New Hires (NDNH), which is a centralized directory of employment and wage information. The information maintained in the NDNH is collected electronically and helps child support agencies locate parents and enforce child support orders. NDNH information is also used for authorized purposes by specific state and federal agencies to help administer certain programs authorized under 42 U.S.C. 653(i)(1).

Respondents: Employers, State Child Support Agencies, and State Workforce Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Rounded number of responses per respondent	Average burden hours per response	Total
New Hire: Employers Reporting Manually	5,265,682	1.39	.025 hours (1.5 minutes)	182,982.45
New Hire: Employers Reporting Electronically	635,049	103.46	.00028 hours (1 second)	18,396.61
New Hire: States	54	135,185.19	.017 hours (1 minute)	124,100.00
Quarterly Wage (QW) & Unemployment Insurance (UI)	53	26.00	.00028 hours (1 second)	0.39
Multistate Employer Registration Form	4,075	1.00	.050 hours (3 minutes)	203.75

Estimated Total Annual Burden Hours: 325,683.

Authorities: 42 U.S.C. 653A(b)(1)(A) and (B); 42 U.S.C. 653A(g)(2)(A); 26 U.S.C. 3304(a)(16)(B); 42 U.S.C. 503(h)(1)(A); and, 42 U.S.C. 653A(g)(2)(B).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–10701 Filed 5–21–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2102]

Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations.'' This draft guidance describes the Agency's recommendations on the design and evaluation of comparative analytical studies intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product licensed under the Public Health Service Act (PHS Act). Additionally, this draft guidance is intended to provide recommendations to sponsors on the scientific and technical information for the chemistry, manufacturing, and controls (CMC) portion of a marketing application for a proposed product submitted under the PHS Act. This draft guidance revises the guidance entitled ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product'' that was published on April 30, 2015.

DATES: Submit either electronic or written comments on the draft guidance by July 22, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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