

**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

comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-2102 for “Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 75, Rm. 6522, Silver Spring, MD 20993-0002, 301-796-1042; or Stephen Ripley, 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 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 section 351(a) of the PHS

Act (42 U.S.C. 262(a)). Additionally, this draft guidance is intended to provide recommendations to sponsors on of the scientific and technical information for the CMC portion of a marketing application for a proposed product submitted under section 351(k) of the PHS Act. Although the 351(k) pathway applies generally to biological products, this guidance focuses on therapeutic protein products.

The Biologics Price Competition and Innovation Act of 2009 was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010, and created an abbreviated licensure pathway under section 351(k) of the PHS Act for biological products demonstrated to be biosimilar to, or interchangeable with, a reference product. Under this abbreviated licensure pathway, FDA will license a proposed biological product submitted under section 351(k) of the PHS Act if, among other things, FDA determines that the information submitted in the application is sufficient to show that the biological product is biosimilar to the reference product.

In the **Federal Register** of February 15, 2012 (77 FR 8884), FDA announced the availability of the draft guidance entitled “Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product.” FDA received a number of comments on the draft guidance. In response to these comments, FDA provided further clarification on the general principles described through a final guidance entitled “Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product,” which was announced in the **Federal Register** of April 30, 2015 (80 FR 24257).

In the **Federal Register** of September 22, 2017 (82 FR 44425), FDA announced the availability of the draft guidance entitled “Statistical Approaches to Evaluate Analytical Similarity.” FDA received a number of comments on the draft guidance. Comments submitted to the docket addressed a range of issues that could impact the cost and efficiency of biosimilar development, including the number of reference product lots the draft guidance would have recommended that biosimilar developers sample in their evaluation of high similarity and the statistical methods for this evaluation. After considering the public comments that FDA received, FDA determined it would withdraw the draft guidance to give further consideration to the scientific and regulatory issues involved. FDA announced the withdrawal of the draft

guidance on June 21, 2018, with the intention of issuing future draft guidance on the evaluation of analytical data to support a demonstration that a proposed biosimilar product is highly similar to a reference product.

This draft guidance revises the guidance issued on April 30, 2015. FDA has adjusted the title of this draft guidance to more clearly communicate that this draft guidance includes 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. In addition to editorial and clarifying edits, the draft guidance includes a section that fulfills the Biosimilar User Fee Act II commitment to publish a revised draft or final guidance, describing statistical considerations for the analysis of analytical similarity data intended to support a demonstration of "highly similar" for biosimilar biological products within 18 months after the close of the public comment period for the withdrawn guidance, "Statistical Approaches to Evaluate Analytical Similarity."

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations, which are not expected to change as a result of the guidance. 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 related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application (BLA) under section 351(a) of the PHS Act, which is covered under

part 601 (21 CFR part 601) and approved under OMB control number 0910–0338; and (4) a BLA under section 351(k), which is covered under part 601 and approved under OMB control number 0910–0719.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: May 16, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Changes to the Scholarships to Disadvantaged Students Program

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Request for public comment on the Scholarships for Disadvantaged Students program.

**SUMMARY:** The Scholarships for Disadvantaged Students (SDS) program is authorized by the Public Health Service Act (PHS Act) and administered by HRSA. The program promotes diversity among the health professions and nursing workforce by providing awards to eligible health professions and nursing schools for use in awarding scholarships to students from disadvantaged backgrounds. This notice seeks public comment to inform and guide policy and planning associated with the SDS program.

**DATES:** Individuals and organizations interested in providing information must submit written comments no later than 11:59 p.m. Eastern Time on June 21, 2019.

**ADDRESSES:** Interested parties should submit their comments to Denise Sorrell, SDS Project Officer, via email at [SDSProgram@HRSA.gov](mailto:SDSProgram@HRSA.gov). Please include the title of this notice, "Request for Comment: SDS Program" in the subject line of the email. Response to this request is voluntary. Responders are free to address any or all of the proposals listed below. This request is for

information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the federal government. All submitted comments will be available to the public in their entirety.

#### FOR FURTHER INFORMATION CONTACT:

Denise Sorrell, SDS Project Officer, Division of Health Careers and Financial Support, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N78, Rockville, Maryland 20857, phone (301) 443–2909, or email [SDSProgram@HRSA.gov](mailto:SDSProgram@HRSA.gov).

**SUPPLEMENTARY INFORMATION:** HRSA is considering updating the SDS program to increase the impact of the program. The authorizing statute allows the Secretary of HHS to make grants to certain health professions and nursing schools that are carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups, to provide scholarships to eligible students (PHS Act, Sec. 737(a), (d)(1)). Grantees provide scholarships to individuals who meet the following requirements: (1) are from disadvantaged backgrounds; (2) have a financial need for a scholarship; and (3) are enrolled (or accepted for enrollment) at an eligible health professions or nursing school as a full-time student in a program leading to a degree in a health profession or nursing (PHS Act, Sec. 737(d)(2)(A–C)). Under the statute, priority is given to eligible entities based on the proportion of graduating students practicing in primary care settings, the proportion of underrepresented minority student enrollees and graduates, and the proportion of graduates working in medically underserved communities (MUCs) (PHS Act, Sec. 737(c)). The PHS Act requires HRSA to award at least 16 percent of the available funds to schools of nursing (PHS Act, Sec. 740(a)).

Eligible applicants are public or non-profit private accredited schools of allopathic medicine, osteopathic medicine, dentistry, nursing, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, chiropractic, or allied health; a school offering a graduate program in behavioral and mental health practice; or an entity providing programs for the training of physician assistants as determined in Section 737(d)(1)(A) of the PHS Act. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply if all other eligibility requirements are met. Additionally, Section 737(d)(2) requires "a school must be carrying out a recruitment and