A contractor will also collect assault injury data from nursing home violent event reports three years pre-regulation (2009–2011) and three years post-regulation (2012–2014). This data will be collected from existing OSHA logs; a NIOSH employee will fill out the Employee Incident Form from the OSHA logs received from the contractor. The purpose of collecting these data is to evaluate changes in assault injury rates before and after enactment of the regulations (Aim 2). The following information will be abstracted from the OSHA logs: Date, time and location of the incident; identity, job title and job task of the victim; identity of the perpetrator; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants, and; actions taken by the facility in response to the incident. No employee or perpetrator identifiable information will be collected.

There are no costs to respondents other than their time. The total estimated burden hours are 120.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per esponse (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Nursing Home Administrator | Interview | 40 | 1 | 1 | 40 |
| Nursing Home Administrator | Abstraction Form | 40 | 1 | 1 | 40 |
| Nursing Home Administrator | Employee Incident Form | 40 | 1 | 1 | 40 |
| Total | | | | | 120 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2015–07038 Filed 3–26–15; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 77 FR 1941, January 12, 2012, and redesignated from Part HN as Part N at 60 FR 56605, November 9, 1995), is amended as set forth below to rename the National Center for Complementary and Alternative Medicine (NCCAM).

Section N–D, Organization and Functions, under the heading National Center for Complementary and Alternative Medicine (NCCAM), is renamed to the National Center for Complementary and Integrative Health (NCCIH).

*Delegations of Authority Statement:* All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this reorganization and are consistent with this reorganization shall continue in effect, pending further redelegation.

Dated: March 20, 2015.

**Francis S. Collins,**

*Director, NIH.*

[FR Doc. 2015–07064 Filed 3–26–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0114]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

**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 information collection requirements relating to the regulations which state that protocols for samples of biological products must be submitted to the Agency.

**DATES:** Submit either electronic or written comments on the collection of information by May 26, 2015.

**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.

**Request for Samples and Protocols—(OMB Control Number 0910–0206)—Extension**

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under 21 CFR 610.2, the Center for Biologics Evaluation and Research (CBER) or the Center for Drugs Evaluation and Research may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: 21 CFR 660.6 (Antibody to Hepatitis B Surface Antigen); 21 CFR 660.36 (Reagent Red Blood Cells); and 21 CFR 660.46 (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After official release is no longer required, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot.

Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of a product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (*e.g.,* Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 80 manufacturers submitted samples and protocols in fiscal year (FY) 2014, under the regulations cited previously in this document. FDA estimates that approximately 76 manufacturers submitted protocols under § 610.2 and 2 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under § 660.36 or § 660.46, however FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2014 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the average burden per response is based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2. FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 610.2 Lot Release Information Submission | 76 | 84.54 | 6,197 | 3 | 18,591 |
| 660.6(b) Lot Release Information Submission | 2 | 9 | 18 | 5 | 90 |
| 660.36(a)(2) and (b) Lot Release Information Submission | 1 | 1 | 1 | 6 | 6 |
| 660.46(b) Lot Release Information Submission | 1 | 1 | 1 | 5 | 5 |
| Total | 80 | | 6,217 | | 18,692 |

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

Dated: March 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–07008 Filed 3–26–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3313–N]**

### Announcement of the Re-Approval of the College of American Pathologists (CAP) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the application of the College of American Pathologists (CAP) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the CAP meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant CAP deeming authority for a period of 6 years.

**DATES:** This notice is effective from March 27, 2015, until March 27, 2021.

**FOR FURTHER INFORMATION CONTACT:** Melissa Singer, 410–786–0365.

**SUPPLEMENTARY INFORMATION:**

#### I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under these provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

#### II. Notice of Approval of CAP as an Accreditation Organization

In this notice, we approve the College of American Pathologists (CAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements in all specialties and subspecialties. We have examined the initial CAP application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the CAP meets or exceeds the applicable CLIA requirements. We have also determined that the CAP will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the CAP approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialties and subspecialties areas under CLIA. As a result of this determination, any laboratory that is accredited by the CAP during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed specialties and subspecialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

#### III. Evaluation of the CAP Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the CAP accreditation program meets the necessary requirements to be approved by CMS as an accreditation program with deeming authority under the CLIA program. The CAP formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

*A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program*

The CAP submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that the CAP's policies and procedures for oversight of laboratories performing all laboratory testing covered by CLIA are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The CAP submitted documentation regarding its requirements for monitoring and inspecting laboratories, and describing its own standards regarding accreditation removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are