

studies or resulted in the production of the drugs affected by the fraud” and that “[t]he drugs produced were free of fraud and material false statements.” Ms. Ngo then asserts that her lack of financial motive for conducting her offense weighs in her favor because “the maximum period of debarment should be reserved for those who profit.”

In determining the period of Ms. Ngo’s debarment, whether she could have been convicted of a felony is not relevant. Under section 306(c)(3) of the FD&C act, FDA considers the nature and seriousness of the offense. Ms. Ngo admitted to knowingly and repeatedly falsifying clinical trial records. Additionally, the inclusion of a provision in Ms. Ngo’s plea agreement that prevents her from engaging in clinical research “during any term of probation or supervised release” evinces concern by the prosecution that she would continue to violate the law if involved in clinical research.

As set forth in the proposal to debar, “[t]he creation and submission of falsified clinical trial data undermines FDA’s determination of safety, effectiveness, and quality of the drugs the studies were designed to assess.” Although the scope of conduct to which Ms. Ngo admitted during the criminal proceedings may have been limited to a few patients, submitting any false or fabricated data to the FDA is a serious offense that compromises the public health. Further, it is irrelevant that Eli Lilly ultimately did not use any of her information “in a detrimental way.” Had Ms. Ngo’s conduct gone undetected and Eli Lilly submitted a new drug application containing the falsified data, FDA might have relied on her fabricated information to approve a new drug product, which reliance could have compromised the public health. Additionally, Ms. Ngo’s lack of financial gain from her conduct does not diminish the nature and seriousness of her offense. Accordingly, Ms. Ngo has failed to create a genuine and material factual dispute with respect to the nature and seriousness of her offense.

Ms. Ngo next argues that, because she has not been involved in clinical trials since entering her guilty plea, there are “reasonable assurances” that “the offense will not happen again.” Ms. Ngo appears to be referencing the consideration under section 306(c)(3)(D) of the FD&C Act, where FDA must consider, *where applicable*, “whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.” The considerations

in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. The consideration at issue does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming for the sake of argument that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, Ms. Ngo offers no actual facts to support her assertion that there are reasonable assurances that the offense will not occur again in the future; therefore, her unsubstantiated contention that, because she has not been involved in clinical trials since entering her guilty plea provides reasonable assurances that she will not commit the offense again, fails to create a genuine and substantial issue of fact that warrants a hearing.

Finally, Ms. Ngo argues that the maximum period of debarment is inappropriate for first-time offenders. While the Agency does consider prior convictions involving matters within the FDA’s jurisdiction under section 306(c)(3)(F) of the FD&C Act, that consideration is only one of several that FDA considers in determining the appropriateness and period of debarment under section 306(c)(3). Ms. Ngo knowingly and repeatedly falsified clinical data records. FDA has determined that the conduct underlying her offense, combined with her failure to take any voluntary steps to mitigate the effect of her offense on the public, is sufficiently serious to warrant a 5-year period of debarment, even though she does not have any prior convictions involving matters within the Agency’s jurisdiction.

### III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under the authority delegated to her by the Commissioner of Food and Drugs, finds: (1) That Ms. Ngo has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Ms. Ngo is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 335, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 2, 2021 (*see* 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Ms. Ngo, in any capacity during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Ngo, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, that person will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Ngo during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: July 27, 2021.

**Denise Hinton,**  
*Chief Scientist.*

[FR Doc. 2021–16352 Filed 7–30–21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2002–N–0314]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by September 1, 2021.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0206. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Request for Samples and Protocols**

*OMB Control Number 0910–0206—Extension*

This information collection supports Agency regulations. 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 § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug 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: §§ 660.6, 660.36, and 660.46 (21 CFR 660.6, 660.36, and 660.46).

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 CBER, 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 CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or 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 the 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 75 manufacturers submitted samples and protocols in fiscal year (FY) 2020 under the regulations cited previously in this document. FDA estimates that approximately 72 manufacturers submitted protocols under § 610.2, and 3 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 2020 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 hour to 5.5 hours. Under § 610.2, the hours per response are 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) because more information is generally required to be submitted in the other protocols than under § 610.2.

In the **Federal Register** of March 16, 2021 (86 FR 14448), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2, Requests for Samples and Protocols; Official Release .....	72	82.972	5,974	3	17,922
660.6(b), Protocols .....	3	4	12	5	60
660.36(a)(2) and (b), Samples and Protocols .....	1	1	1	6	6
660.46(b), Protocols .....	1	1	1	5	5
Total .....	77	.....	5,988	.....	17,993

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: July 27, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

**FOR FURTHER INFORMATION CONTACT:** Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240-276-2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

**SUPPLEMENTARY INFORMATION:** In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories

and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at <https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list>.

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory

Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

#### HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

#### HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780-784-1190 (Formerly: Gamma-Dynacare Medical Laboratories)