Todd.Lertjuntharangool@acf.hhs.gov, or phone (202) 205–9503. Additional information and online meeting registration will be available at *https://eclkc.ohs.acf.hhs.gov/about-us/article/2020-tribal-consultations.*

SUPPLEMENTARY INFORMATION: In accordance with Section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces OHS Tribal Consultation Sessions for leaders of tribal governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS tribal consultations in Glendale, Arizona; Spokane, Washington; and Denver, Colorado, will be organized around the statutory purposes related to meeting the needs of AIAN children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken, and in progress, to address the issues and concerns raised in the 2019 OHS Tribal Consultations.

The consultation sessions will be conducted with elected or appointed leaders of tribal governments and their designated representatives. Designees must have a letter from the tribal government authorizing them to represent the tribe. Tribal governments must submit the designee letter at least 3 days in advance of the consultation sessions to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov.* Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each tribal consultation session will be prepared and made available within 45 days of the session to all tribal governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov,* prior to each consultation session or within 30 days after each meeting.

OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Megan E. Steel,

Executive Secretariat Certifying Officer.

[FR Doc. 2020–10440 Filed 5–14–20; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6085]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Practice and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

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 0910–0191. 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, *PRAStaff@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.

General Administrative Practice and Procedures

OMB Control Number 0910–0191—Revision

This information collection supports FDA regulations governing its administrative practices and procedures. Although certain information collection pertaining to official administrative actions is not subject to review by OMB under the PRA in accordance with 44 U.S.C. 3518(c)(1)(B) (5 CFR 1320.4(a)(2)), we have reviewed our regulations and are revising this information collection to include provisions that we believe may be subject to OMB review. We are also revising the information collection to consolidate related activities discussed in Agency guidance, as we believe this will improve the efficiency of our operations.

In the **Federal Register** of January 9, 2020 (85 FR 1169), we published a 60-day notice soliciting comment on the proposed collection of information. Although two comments were received, neither was directly responsive to the information collection topics solicited. At the same time, the comments were supportive of FDA information collection activity, and we appreciate this input.

We estimate the burden of the 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
10.19; request for waiver, suspension, or modification of requirements	1	1	1	1	1
10.30 and 10.31; citizen petitions and petitions related to ANDA,[2] certain NDAs,[3] or certain BLAs[4]	220	1	220	24	5,280
10.33; administrative reconsideration of action	6	1	6	10	60
10.35; administrative stay of action	5	1	5	10	50
10.65; meetings and correspondence	750	1	750	5	3,750
10.85; requests for Advisory opinions	4	1	4	16	64
10.115(f)(3); submitting draft guidance proposals	100	1	100	4	400

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
12.22—Filing objections and requests for a hearing on a regulation or order	5	1	5	20	100
12.45—Notice of participation	5	1	5	3	15
Total			1,096		9,720

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Abbreviated new drug applications.
[3] New drug applications.
[4] Biologic license applications.

Unless a waiver, suspension, or modification submitted under § 10.19 (21 CFR 10.19) is granted by the Commissioner of Food and Drugs (the Commissioner), the regulations in 21 CFR part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because we have not received requests under § 10.19, we had not included this provision in the information collection. However, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually.

Administrative proceedings may be initiated under § 10.25 (21 CFR 10.25) when a petition is submitted. Section 10.30 (21 CFR 10.30) sets forth procedures by which an interested person may submit a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. Similarly, § 10.31 (21 CFR 10.31) governs citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)). The regulations provide content, format, and procedural requirements applicable to the submission of these petitions. To assist respondents to the information collection, FDA's Center for Drug Evaluation and Research developed an interpretive guidance entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' The guidance describes FDA's current thinking on interpreting section 505(q) of the FD&C Act (21 U.S.C. 355(q)), and is currently approved under OMB control number 0910–0679. Based on Agency data, an average of 220 citizen petitions are received annually under §§ 10.30 and 10.31, and we estimate an average of 24 hours is required to prepare such a petition, for a total of 5,280 hours annually.

The regulations also establish a means by which an interested person may request that part or all of a decision by the Commissioner be reconsidered, or that the effective date of an action be stayed or extended. Sections 10.33 and 10.35 (21 CFR 10.33 and 10.35) establish the content, format, and procedural requirements applicable to such requests and explain that they must be submitted no later than 30 days after the decision involved. The regulations provide alternatively that, for good cause, the Commissioner may permit a petition to be filed after 30 days. The regulations also explain that an interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. According to our records, we have received a total of 12 such requests and we assume it takes respondents an average of 10 hours to prepare.

Section 10.65 (21 CFR 10.65) covers Agency meetings and correspondence. Interested persons may hold meetings and exchange correspondence with FDA representatives on matters within its jurisdiction by following the instructions and providing the information described in § 10.65. Because FDA maintains other information collections in its inventory that cover specific types of meeting requests, we did not previously include burden that may result from this section. However, to account for burden associated with meeting requests and correspondence generally, we provide an estimate of 750 submissions annually under this information collection; we assume one respondent per submission; and we assume each submission requires respondents between 1 to 10 hours to prepare, including gathering and reviewing the necessary material. We therefore use an average of 5 hours for this estimate and base this estimate on our experience with similar information collection.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act, sets forth content, format, and procedural requirements by which an interested person may request an advisory opinion from the Commissioner on a matter of general applicability. The regulation explains that, when making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Based on Agency data, we estimate four such requests are received each year, and we assume each request requires 16 hours to prepare, for a total of 64 hours annually.

Section 10.115(f)(3) (21 CFR 10.115(f)(3)) provides for the public submission of draft guidance documents or topics for development to our Dockets Management Staff. To participate in the development and issuance of guidance documents, the public may elect to submit comment through alternative mechanisms as explained in our Good Guidance Practice regulations under § 10.115. Although most submissions and attendant burden associated with recommendations found in Agency guidance is accounted for in individual information collections associated with a particular product area or regulatory topic, here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3). Based on Agency data, we receive an average of 100 such submissions each year; we assume each submission requires an average of 4 hours to prepare and, therefore, calculate a total burden of 400 hours annually.

Regulations in § 12.20 (21 CFR 12.20) include information collection associated with requesting a formal evidentiary public hearing and are issued under section 701(e)(2) of the

FD&C Act. The regulations provide instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted. We estimate five respondents will file a request under the regulation and assume each request requires 20 hours to prepare, for a total of 100 hours annually.

Finally, § 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth content, format, and procedural requirements for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance. Based on our records, we estimate five filings under this regulation and assume it requires 3 hours to prepare, for a total of 15 hours annually.

Respondents to the information collection are those interested persons conducting business with FDA, and thus subject to the applicable administrative regulations.

The burden estimates for this collection of information are based on Agency records and our experience over the past 3 years. By revising the information collection to include additional provisions, we have increased our annual burden estimate by 869 responses and 1,096 hours.

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10384 Filed 5–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0987]

Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency; Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff; 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 final guidance entitled ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.'' On February 4, 2020, the Secretary of Health and Human Services (HHS) determined that there is a public health emergency and that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV). Rapid detection of Coronavirus Disease-2019 (COVID–19) cases in the United States requires wide availability of SARS-CoV–2 testing. This guidance was revised on March 16, 2020, May 4, 2020, and May 11, 2020. The guidance describes four policies intended to help facilitate the development and use of SARS-CoV–2 tests during the public health emergency: Two policies for accelerating the development of certain laboratory tests for COVID–19—one leading to an Emergency Use Authorization (EUA) submission to FDA and the other not leading to an EUA submission when the test is developed under the authorities of the State in which the laboratory resides and the State takes responsibility for COVID–19 testing by laboratories in its State; a policy for commercial manufacturers to more rapidly distribute their SARS-CoV–2 diagnostics to laboratories for specimen testing after validation while an EUA submission is being prepared for submission to FDA; and a policy regarding the use of serological testing. In addition, FDA has included a reference to the availability, on FDA's website, of templates for commercial manufacturers and laboratories intended to facilitate EUA submissions for molecular, antigen, and serology tests. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on May 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–0987 for ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.'' Received comments will be placed in the docket