collection, changes compared to before COVID–19 began, and what has been challenging or worked well. The study will use surveys and interviews with center directors, FCC providers, and coaches. The sample frame will be comprised of respondents to the 2019 survey.

Respondents: ECE center directors, coaches, and FCC providers who responded to 2019 SCOPE surveys.

Annual Burden Estimates

Data collection will be completed within a 1-year period.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average Burden per response (in hours)	Total/Annual burden (in hours)
Coach Survey (Instrument 1)	100	1	.33	33
Center Director Survey (Instrument 2)	66	1	.33	22
FCC Provider Survey (Instrument 3)	38	1	.33	13
Coach Interview (Instrument 4)	12	1	.75	9
Center Director Interview (Instrument 5)	24	1	.75	18
FCC Provider Interview (Instrument 6): FCC providers	12	1	.75	9

Estimated Total Annual Burden Hours: 104.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9858(a)(5), 42 U.S.C. 9835, and 42 U.S.C. 9844.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–28043 Filed 12–18–20; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration-Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 January 20, 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 0910–0498. 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.

Export of Food and Drug Administration-Regulated Products: Export Certificates

OMB Control Number 0910–0498—Extension

Sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382) pertain to the export of FDA-regulated products and are intended to ease restrictions on exportation. The provisions also require the Agency to issue written export certifications within 20 days of any request. In January 2011, section 801(e)(4)(A) was amended by the FDA Food Safety Modernization Act (Pub. L. 111–353) to provide authorization for export certification for food and animal feed, as well as certain unapproved products. To offset Agency resource expenditures for processing certifications requests, the statute provides that FDA may charge firms a fee not to exceed $175.

There are four FDA forms (Form FDA 3613, 3613a, 3613b, and 3613c) related to exporting FDA-regulated products. A description of each form is provided below. To obtain a fillable PDF file of each form, visit *https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/fda-forms-certificates-exporting.* To learn more about how to complete these forms, visit *https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/how-complete-fda-export-certificate-forms.*

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
''Supplementary Information Certificate to Foreign Government Requests''.	For the export of products legally marketed in the United States.
''Exporter's Certification Statement Certificate to Foreign Government''.	
''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''..	
''Supplementary Information Certificate of Exportability Requests''	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
Exporter's Certification Statement Certificate of Exportability''.	
''Supplementary Information Certificate of a Pharmaceutical Product'' ...	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
''Exporter's Certification Statement Certificate of a Pharmaceutical Product''.	
''Supplementary Information Non-Clinical Research Use Only Certificate''.	For the export of a non-clinical research use only product, material, or component that is not intended for human use and which may be marketed in, and legally exported from the United States under the FD&C Act.
''Exporter's Certification Statement (Non-Clinical Research Use Only)''	

Appropriate centers within FDA review product information submitted by firms in support of the firms' certificate requests. We rely on respondents to certify their compliance with all applicable requirements of the FD&C Act both at the time the certification request is submitted to FDA and at the time the certification is submitted to the respective foreign government. Information regarding FDA's Export Certificates may be found on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates.*

On September 16, 2020, we submitted an information collection request to the Office of Management and Budget (OMB) to revise certain data elements as may be applicable under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Because Section 3856 of the CARES Act contained immediately effective provisions obligating FDA to review and process certification requests, we requested emergency processing by OMB under 5 CFR 1320.13 for the respective information collection. Our information collection request was granted by OMB on September 29, 2020. Therefore, in accordance with 5 CFR 1320.8(d)(1), we invite comment on the burden we attribute to the information collection, which we estimate as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA center	Number of Respondents	Number of Responses per Respondent	Total Anual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research	3,680	1	3,680	1	3,680
Center for Veterinary Medicine	1,925	1	1,925	1	1,925
Total	.....	.....	.....	.....	30,606

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

Based on our current evaluation of the information collection, we have made no adjustments since our last request for OMB review and approval.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28064 Filed 12–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2217]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 reporting and recordkeeping requirements of our regulations concerning new animal drugs for investigational use.

DATES: Submit either electronic or written comments on the collection of information by February 19, 2021.