importation; facility isolation and containment information; and personnel qualifications. CDC plans to make no changes to this application.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to make no changes to this application.

Estimates of burden for the survey are based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010. The total estimated burden for the one-time data collection is 545 hours. There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors.	Application for Permit to Import Infectious Biological Agents into the United States.	1625	1	20/60
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats ..	10	1	20/60

Jeffrey M. Zirger,

Health Scientist, Acting 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. 2016–19598 Filed 8–16–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Migrant and Seasonal Head Start Study.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing an information collection activity for the Migrant and Seasonal Head Start (MSHS) Study.

The MSHS Study is a nationally representative study that will describe the characteristics and experiences of the children and families who enroll in MSHS and the practices and services of the MSHS programs that serve them. The findings will provide essential up-to-date information to the Office of Head Start, other federal government agencies, local MSHS programs, and the public. The study will be the first national MSHS study to include direct child assessments, which will provide valuable information about MSHS children that programs can use to inform program, center and classroom practices.

Data collection will involve mail surveys to selected MSHS center directors and all MSHS program directors nationwide about operational characteristics, program- and center-level policies and practices, and services and resources offered to MSHS families. The study will also conduct on-site data collection with children, parents, teachers, and classrooms in a nationally-representative sample of MSHS centers. The on-site data collection will include classroom observations, teacher surveys, child reports and child assessments to obtain information on classroom instruction and practices, children's abilities and families' well-being.

Respondents: MSHS program directors, center directors, teachers, assistant teachers, parents, and children.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Program Director survey	53	1	0.67	36
Center Director survey	253	1	0.67	170
Call script for Program Directors	24	1	1	24
Form for Program Directors to verify key information for selected centers ..	24	1	0.5	12
Call script for Center Directors	53	1	1	53
Call script for On Site Coordinators	53	1	1	53
Classroom sampling form	53	1	0.5	27
Data collection coordination efforts	53	1	20	1,060
Child roster form	53	3	0.25	40
Teacher survey	159	1	0.67	107
Teacher child report	159	8	0.17	216
Assistant Teacher survey	159	1	0.33	52
Parent consent form	1,018	1	0.25	255
Child assessments (preschoolers and older toddlers only)	848	1	0.67	568
Parent interview (including Parent child report)	1,018	1	1	1,018
Estimated Total Annual Burden Hours:	.....	.....	.....	3,689

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2016–19611 Filed 8–16–16; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0800]

Regulatory Classification of Pharmaceutical Co-Crystals; 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 ''Regulatory Classification of Pharmaceutical Co-Crystals.'' This guidance provides applicants planning to submit new drug applications (NDAs) and abbreviated new drug applications (ANDAs) with information on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data that applicants should submit to support the appropriate classification of a co-crystal as well as the regulatory implications of the classification. This draft guidance revises the guidance for industry entitled ''Regulatory Classification of Pharmaceutical Co-Crystals'' issued in April 2013.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 17, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2011–D–0800 for ''Regulatory Classification of Pharmaceutical Co-Crystals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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