American Academy of Pediatrics (AAP) with support from CDC. The curriculum uses a Train-the-Trainer model whereby attending physicians at developmental continuity clinics receive in-depth training and then facilitate training of first-year pediatric residents in their own clinics.

In Phase One, training for attending physicians will be organized around four presentations by experts in the identification, diagnosis, and care of children with FASD and their families. Pre/post-test assessments will be obtained for each presentation, followed by an overall assessment at the end of the training day.

In Phase Two, the attending physicians will implement a curriculum of continuing medical education activities with their first-year pediatric residents. Required activities for residents include viewing three pre-recorded video presentations. Changes in residents' knowledge of training content will be assessed both before and after the video presentations.

Pre/post-test data will be collected through paper-and-pencil surveys for in-person training of attending physicians, and by secure email for resident trainees. Attending physicians will also be asked to participate in a final project debriefing conference call.

The purpose and use of the assessment data will be to assure that specific information in the FASD training curriculum is conveyed and understood by participants. The public health goal is to strengthen the identification, referral, and care of children with prenatal exposure to alcohol.

OMB approval is requested for three years. Approximately 10 clinics will be recruited each year. Respondents will be one attending physician per clinic, and approximately 25 pediatric residents per clinic. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 223 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Pediatrician (Attending Physician) ...	Attending Physicians Screening & Diagnosis Pretest ..	10	1	10/60
	Attending Physicians Screening & Diagnosis Posttest	10	1	10/60
	Attending Physicians Treatment Across Lifespan Pretest.	10	1	10/60
	Attending Physicians Treatment Across Lifespan Posttest.	10	1	10/60
	Attending Physicians Overcoming Social Attitudes Pretest.	10	1	10/60
	Attending Physicians Overcoming Social Attitudes Posttest.	10	1	10/60
	Attending Physicians Educational Care Pretest	10	1	10/60
	Attending Physicians Educational Care Posttest	10	1	10/60
	Attending Physicians Training Program Assessment ...	10	1	15/60
	Attending Physicians Overall Program Assessment	10	1	20/60
	Attending Physicians Debriefing Guide	10	1	1
	Attending Physicians Application (A15)	10	1	10/60
Pediatrician (Resident)	Resident Overall Effects & Prevalence Video Pretest	250	1	15/60
	Resident Overall Effects & Prevalence Video Posttest	250	1	15/60
	Resident Overall Program Assessment	250	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–15227 Filed 7–16–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Cilastatin Sodium; Imipenem; Relebactam; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (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 ''Draft Guidance for Cilastatin Sodium; Imipenem; Relebactam.'' The draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for cilastatin sodium; imipenem; relebactam for injection.

DATES: Submit either electronic or written comments on the draft guidance by September 17, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2007–D–0369 for ''Draft Guidance for Cilastatin Sodium; Imipenem; Relebactam.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398 and/or *PSG-QUESTIONS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft guidance on a generic Cilastatin Sodium; Imipenem; Relebactam for injection.

FDA initially approved new drug application 212819 RECARBRIO (cilastatin sodium; imipenem; relebactam for injection) in July 2019. We are now issuing a draft guidance for industry on generic cilastatin sodium; imipenem; relebactam for injection (''Draft Guidance on Cilastatin Sodium; Imipenem; Relebactam'').

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on, among other things, the design of BE studies to support ANDAs for cilastatin sodium; imipenem; relebactam for injection. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 12, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15170 Filed 7–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of