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Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for “Draft Guidance for Cilastatin Sodium; Imipenem; Relebactam.”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 publically 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 PSQ-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.regulations.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. FDA is publishing this draft guidance documents at https://www.regulations.gov.

Dated: July 12, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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
SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 et seq., provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following: 1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and 2. Any allegation in a petition that the petitioner either:
   a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or
   b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading FOR FURTHER INFORMATION CONTACT), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857. The Court’s caption (Petitioner’s Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

**List of Petitions Filed**

4. Lydia M. Goode, Greensboro, North Carolina, Court of Federal Claims No: 21–1307V
6. Chad Adaway, Birmingham, Alabama, Court of Federal Claims No: 21–1311V
7. John Buen, Boston, Massachusetts, Court of Federal Claims No: 21–1314V
10. Ciara Johnson, Durango, Colorado, Court of Federal Claims No: 21–1317V
11. Lindsay Walker on behalf of R.W., Aurora, Colorado, Court of Federal Claims No: 21–1318V
13. Debbie L. Tice, Jackson, Mississippi, Court of Federal Claims No: 21–1322V
15. Janice Walker, Ventura, California, Court of Federal Claims No: 21–1325V
19. Marlena Lloyd and Jeffrey Lloyd on behalf of C.L., Boston, Massachusetts, Court of Federal Claims No: 21–1332V
20. Keith Montague, Boston, Massachusetts, Court of Federal Claims No: 21–1333V
22. Jennifer Huch and Lucas Huch on behalf of L.L., Bedford, Texas, Court of Federal Claims No: 21–1335V
23. Michelle Gill on behalf of A.G., Phoenix, Arizona, Court of Federal Claims No: 21–1336V
29. Michael Williamson, Murfreesboro, Tennessee, Court of Federal Claims No: 21–1346V
30. John Allain, Sulphur, Louisiana, Court of Federal Claims No: 21–1349V
31. Jennifer Clark, Chattanooga, Tennessee, Court of Federal Claims No: 21–1350V
32. Robert Silver, Shelby, North Carolina, Court of Federal Claims No: 21–1351V
33. Kelsey Hamonds, Edgewood, Kentucky, Court of Federal Claims No: 21–1352V
34. Mindy Schuehrer, Marie, Michigan, Court of Federal Claims No: 21–1353V
35. Hortencia Torres, Annandale, Virginia, Court of Federal Claims No: 21–1356V
DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OMB #0990–0475]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 17, 2021.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and use of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

SYNOPSIS:

COVID–19 Attitudes and Beliefs Survey (CABS)

The CABS is a longitudinal survey that will be fielded tri-annually to 4,000 U.S. adults over two years (six waves) via NORC at the University of Chicago's AmeriSpeak Panel. The survey will be fielded online, and each fielding period will last between 3 and 6 weeks. Those that respond to wave 1 of the survey will be recontacted in each wave, facilitating a comparison of COVID–19 behavior change over time for a representative sample and evaluation of U.S. adults. Panel members selected to participate in the study will receive one pre-invitation postcard in the mail, one email invitation, and three email reminders to complete the survey in each wave.

Monthly Outcome Survey (MOS)

The MOS is a cross-sectional survey that will be fielded monthly to 5,000 U.S. adults over two years (24 waves) via the Ipsos KnowledgePanel 5k Omnibus Survey. The survey will be fielded online, and each fielding period will last between 7 and 10 days.