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Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance for Cilastatin Sodium; Imipenem; Relebactam.''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

Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

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) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on June 1, 2021, through June 30, 2021. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

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, 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.

Diana Espinosa,

Acting Administrator.

List of Petitions Filed

1. Kelly Hannon, Washington, District of Columbia, Court of Federal Claims No: 21–1304V
2. Margaret Hoyt, Washington, District of Columbia, Court of Federal Claims No: 21–1305V
3. Sarah Lopez, Washington, District of Columbia, Court of Federal Claims No: 21–1306V
4. Lydia M. Goode, Greensboro, North Carolina, Court of Federal Claims No: 21–1307V
5. Jonathan Jarog, Chicago, Illinois, Court of Federal Claims No: 21–1308V
6. Chad Adaway, Birmingham, Alabama, Court of Federal Claims No: 21–1311V
7. John Buen, Boston, Massachusetts, Court of Federal Claims No: 21–1314V
8. Robert Ben, Colorado Springs, Colorado, Court of Federal Claims No: 21–1315V
9. David Plaut, Fort Collins, Colorado, Court of Federal Claims No: 21–1316V
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
12. Dana Hilden, Phoenix, Arizona, Court of Federal Claims No: 21–1321V
13. Debbie L. Tice, Jackson, Mississippi, Court of Federal Claims No: 21–1322V
14. Rhonda Boyd, Huntsville, Alabama, Court of Federal Claims No: 21–1323V
15. Janice Walker, Ventura, California, Court of Federal Claims No: 21–1325V
16. Mary Patricia Turner, Washington, District of Columbia, Court of Federal Claims No: 21–1327V
17. Kara Mahuron, Washington, District of Columbia, Court of Federal Claims No: 21–1328V
18. Estate of James Leroy Doebler, Deceased, Pascagoula, Mississippi, Court of Federal Claims No: 21–1331V
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
21. Daniel Murphy, Philadelphia, Pennsylvania, Court of Federal Claims No: 21–1334V
22. Jennifer Huch and Lucas Huch on behalf of L.L.L.H., 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
24. Thomas Burbank, Plainville, Connecticut, Court of Federal Claims No: 21–1337V
25. Clifton Foley and Kelli Foley on behalf of N.F., Deceased, Burlington, North Carolina, Court of Federal Claims No: 21–1338V
26. Juanita Artman, Washington, District of Columbia, Court of Federal Claims No: 21–1340V
27. Ramon K. Jusino and Ann M. Jusino on behalf of W.J., Staten Island, New York, Court of Federal Claims No: 21–1342V
28. Nardia Thompson Harris, Nanuet, New York, Court of Federal Claims No: 21–1345V
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

36. Laurel Bennett, Washington, District of Columbia, Court of Federal Claims No: 21–1357V
37. Marie Tully, Washington, District of Columbia, Court of Federal Claims No: 21–1358V
38. Donna Fulbright, Washington, District of Columbia, Court of Federal Claims No: 21–1359V
39. Jovonna Beyer, New York, New York, Court of Federal Claims No: 21–1362V
40. Richard Munoz, Plant City, Florida, Court of Federal Claims No: 21–1369V
41. Josephine Feitel, Georgetown, Texas, Court of Federal Claims No: 21–1370V
42. Austin Reid, Louisville, Kentucky, Court of Federal Claims No: 21–1374V
43. Elizabeth Fellows, Kansas City, Missouri, Court of Federal Claims No: 21–1378V
44. Stephen R. Hunt, Athens, Ohio, Court of Federal Claims No: 21–1379V
45. Raymond Milligan, Jr., Sulphur Springs, Texas, Court of Federal Claims No: 21–1382V
46. Tina Paxson, Bloomington, Indiana, Court of Federal Claims No: 21–1383V
47. Rashawnda L. Benton, Greensboro, North Carolina, Court of Federal Claims No: 21–1384V
48. Jerome Dacurawat, Alexandria, Virginia, Court of Federal Claims No: 21–1389V
49. Krystal Kilgore, Morristown, Tennessee, Court of Federal Claims No: 21–1390V
50. Jeffrey A. Ridenour, Lima, Ohio, Court of Federal Claims No: 21–1392V
51. Lori Kathleen Ogden Erickson, Milton, Washington, Court of Federal Claims No: 21–1395V
52. Angela Saporito, Nutley, New Jersey, Court of Federal Claims No: 21–1398V
53. Shawn Wilson-Blount, White Plains, New York, Court of Federal Claims No: 21–1400V
54. Geeta Karra, Philadelphia, Pennsylvania, Court of Federal Claims No: 21–1402V
55. Jonathan Charter, Manchester, Connecticut, Court of Federal Claims No: 21–1404V
56. Tammy Walden on behalf of J.F., Phoenix, Arizona, Court of Federal Claims No: 21–1406V
57. Bruce A. Ades, Denver, Colorado, Court of Federal Claims No: 21–1407V
58. Wendy O'Neil, Englewood, New Jersey, Court of Federal Claims No: 21–1410V

[FR Doc. 2021–15223 Filed 7–16–21; 8:45 am]

BILLING CODE 4165–15–P

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: When submitting comments or requesting information, please include the document identifier 0990–0475–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: 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 utility 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.

Title of the Collection: ASPA COVID–19 Public Education Campaign Evaluation Surveys.

Type of Collection: Extension.

OMB No.: 0990–0475.

Abstract: The Office of the Assistant Secretary for Public Affairs (ASPA), U.S. Department of Health and Human Services (HHS) is requesting an extension on a currently approved collection including two components: 1. COVID–19 Attitudes and Beliefs Survey (CABS), and 2. Monthly Outcome Survey (MOS). Throughout execution of the campaign, this information will primarily be used by ASPA to determine whether the campaign is having the intended impact on target audiences' knowledge, attitudes, and beliefs as they relate to COVID–19, COVID–19 vaccination, and adherence to preventative behaviors. It will also keep key stakeholders informed of the Campaign's progress. Ultimately, the data will inform a thorough evaluation of the efficacy of the campaign and its impact on vaccine uptake.

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.

ANNUALIZED BURDEN HOUR TABLE

	CABS	MOS
Hours to complete survey	0.58	0.17
Participants (per wave)	4,000	5,000
Number of waves (per year)	3	12
Total respondents per year	12,000	60,000
Total burden hours per year	6,960	10,200