knowingly and intentionally attempting to import into the United States a mixture and substance containing a detectable amount of gamma-Hydroxybutyric Acid, a Schedule I controlled substance in violation of 21 U.S.C. 952(a), 960(a)(1), 960(b)(3), and 963 on or about April 16, 2018, as described in the Superseding Indictment in his case dated October 10, 2018.

As a result of this conviction, FDA sent Mr. Jodoin by certified mail on September 25, 2019, a notice proposing to debar him for 5 years from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Jodoin's felony conviction was for conduct relating to the importation into the United States of any drug or controlled substance because he smuggled into the United States a Schedule I controlled substance. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Jodoin's offense and concluded Mr. Jodoin's felony offense warranted a 5-year period of debarment.

The proposal informed Mr. Jodoin of the proposed debarment and offered Mr. Jodoin an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Jodoin received the proposal and notice of opportunity for a hearing on October 8, 2019. Mr. Jodoin failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jodoin has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that this offense should be accorded a debarment period of 5 years.

As a result of the foregoing finding, Mr. Jodoin is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Jodoin is a prohibited act.

Any application by Mr. Jodoin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–2734 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05444 Filed 3–16–20; 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 of 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 February 1, 2020, through February 29, 2020. 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.

Dated: March 11, 2020.

Thomas J. Engels,

Administrator.

List of Petitions Filed

1. Megan Sebasky, Madison, Wisconsin, Court of Federal Claims No: 20–0122V
2. Dorothy Stradford, Hillside, New Jersey, Court of Federal Claims No: 20–0124V
3. Tammie Attaway, Salinas, California, Court of Federal Claims No: 20–0125V
4. Linda Fletcher, Port St. Lucie, Florida, Court of Federal Claims No: 20–0127V
5. Michael Cook, Zionsville, Indiana, Court of Federal Claims No: 20–0128V
6. Tammy Kleyle on behalf of A. N. K., Marrero, Louisiana, Court of Federal Claims No: 20–0129V
7. Julia Conroy, Tucson, Arizona, Court of Federal Claims No: 20–0131V
8. Edwin John Sherry and Kimberly Diane Sherry on behalf of Anjalie Leana-Rose Sherry, Deceased, Charlotte, North Carolina, Court of Federal Claims No: 20–0132V
9. Dan Noel and Haley Noel on behalf of H. N., Colorado Springs, Colorado, Court of Federal Claims No: 20–0134V
10. Ronald Piccolotti, Dallas, Texas, Court of Federal Claims No: 20–0135V
11. Christine Schultz, Frederick, Maryland, Court of Federal Claims No: 20–0136V
12. Katherine Mensinger on behalf of The Estate of Thomas Mensinger, Deceased, Benton Harbor, Michigan, Court of Federal Claims No: 20–0138V
13. Katelyn Uglialoro on behalf of LinMarie Uglialoro, Hershey, Pennsylvania, Court of Federal Claims No: 20–0139V
14. Carol Joan Gonzales, Puyallup, Washington, Court of Federal Claims No: 20–0140V
15. Neil Silver, New York, New York, Court of Federal Claims No: 20–0141V
16. Jeffrey E. Olson, Deceased, Waupun, Wisconsin, Court of Federal Claims No: 20–0142V
17. Joel Miles, Green Bay, Wisconsin, Court of Federal Claims No: 20–0146V
18. Enye McHugh on behalf of S. M., Madison, Wisconsin, Court of Federal Claims No: 20–0148V
19. Francis E. Sethman, Jr., Greensboro, North Carolina, Court of Federal Claims No: 20–0149V
20. Nancy Bender-Kelner, Shorewood, Minnesota, Court of Federal Claims No: 20–0151V
21. Maureen Miller, Berkeley, California, Court of Federal Claims No: 20–0152V
22. Sarah Eichorn, Des Moines, Iowa, Court of Federal Claims No: 20–0154V
23. Rebecca Viancourt, Cleveland, Ohio, Court of Federal Claims No: 20–0155V
24. Heidi M. Brill on behalf of A. B., Fond du Lac, Wisconsin, Court of Federal Claims No: 20–0156V
25. Mario A. Flores, Jr., Harlingen, Texas, Court of Federal Claims No: 20–0157V
26. Pamela M. Leathers, Camas, Washington, Court of Federal Claims No: 20–0162V
27. Ania Oliva-Guedes, Rochester, New York, Court of Federal Claims No: 20–0165V
28. Julie Lechner, Aberdeen, South Dakota, Court of Federal Claims No: 20–0170V
29. Helane Stein, Conshohocken, Pennsylvania, Court of Federal Claims No: 20–0171V
30. Lee Ann Sender, Washington, District of Columbia, Court of Federal Claims No: 20–0172V
31. Jeffrey Horning, Washington, District of Columbia, Court of Federal Claims No: 20–0173V
32. Jakeisha Saville, Dallas, Texas, Court of Federal Claims No: 20–0174V
33. Robert Introini, Mansfield, Massachusetts, Court of Federal Claims No: 20–0176V
34. Dustin Gibson, Humboldt, Iowa, Court of Federal Claims No: 20–0177V
35. Kamalika Saha, Cambridge, Massachusetts, Court of Federal Claims No: 20–0178V
36. Leticia Palencia on behalf of C. A. P., Harlingen, Texas, Court of Federal Claims No: 20–0180V
37. John Gavin, Washington, District of Columbia, Court of Federal Claims No: 20–0181V
38. Hilary Harris, Washington, District of Columbia, Court of Federal Claims No: 20–0182V
39. John Holloway, Oakland, California, Court of Federal Claims No: 20–0184V
40. Marylou LaLonde, Boston, Massachusetts, Court of Federal Claims No: 20–0186V
41. Gary Allen, Idaho Springs, Colorado, Court of Federal Claims No: 20–0187V
42. Rina Schnaufer, Rochester, New York, Court of Federal Claims No: 20–0189V
43. Rodney Koehl, Peoria, Illinois, Court of Federal Claims No: 20–0190V
44. Gelacio Valdez, Dixon, Illinois, Court of Federal Claims No: 20–0191V
45. Montana Smithey on behalf of E. S., Burlington, North Carolina, Court of Federal Claims No: 20–0192V
46. Joseph Dweck, Brooklyn, New York, Court of Federal Claims No: 20–0193V
47. Jennifer Bonilla-Edgington, Stroudsburg, Pennsylvania, Court of Federal Claims No: 20–0194V
48. Brenda Anderson, Grand Rapids, Michigan, Court of Federal Claims No: 20–0195V
49. Betty A. Dennis on behalf of Estate of Richard P. Dennis, Deceased, La Crosse, Wisconsin, Court of Federal Claims No: 20–0198V
50. Nicole Matley, Monroe, Wisconsin, Court of Federal Claims No: 20–0199V
51. Betty Davis, Decatur, Texas, Court of Federal Claims No: 20–0201V
52. Esther Reeves, Naples, Florida, Court of Federal Claims No: 20–0202V
53. Sandeep Bains, Abington, Pennsylvania, Court of Federal Claims No: 20–0203V
54. John Davenport, Tucson, Arizona, Court of Federal Claims No: 20–0206V
55. Phyllis Doyle, Seattle, Washington, Court of Federal Claims No: 20–0207V
56. David Carpenter, Jr., Nashville, Tennessee, Court of Federal Claims No: 20–0208V
57. Tracy Sue Beach, Newark, Ohio, Court of Federal Claims No: 20–0209V
58. Lindsay Corum on behalf of the Estate of Stephen M. Corum, Deceased on behalf of the Estate of Marshall Wayne Corum, Deceased, Henderson, Kentucky, Court of Federal Claims No: 20–0210V
59. Trina Lower, Moose Lake, Minnesota, Court of Federal Claims No: 20–0211V
60. Robert Clendaniel, Millville, New Jersey, Court of Federal Claims No: 20–0213V
61. Wayne Phillip Anderson, Bellevue, Washington, Court of Federal Claims No: 20–0214V
62. Patricia Alex Freeman, North Bend, Washington, Court of Federal Claims No: 20–0215V
63. Raymond Small, Harleysville, Pennsylvania, Court of Federal Claims No: 20–0216V
64. Susie Bjalobok, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20–0217V
65. Jennifer Kilgrow, Salt Lake City, Utah, Court of Federal Claims No: 20–0218V
66. Ignacio Montes, Fontana, California, Court of Federal Claims No: 20–0219V
67. Adam Mackay, Dresher, Pennsylvania, Court of Federal Claims No: 20–0220V
68. Patricia Lopez, Brownsville, Texas, Court of Federal Claims No: 20–0223V
69. Selina Villafranca on behalf of N. L. V., Brownsville, Texas, Court of Federal Claims No: 20–0224V
70. Kim Warner on behalf of D. W., Dublin,

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html,* accessed 27Feb2020,