

application, 510(k) submission, IDE application, and De Novo requests) to demonstrate EMC for electrically powered medical devices and medical devices with electrical or electronic functions. Typically, the review of EMC information in a submission is based on the risk associated with malfunction or degradation of the medical device under consideration, where malfunction or degradation could be caused by inadequate EMC. The review is also based on the use of appropriate consensus standards. This draft guidance is intended to replace “Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices” published July 11, 2016. This draft guidance is not intended to change current policy, but to provide specific technical information to address the recommendations in the 2016 EMC guidance.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will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 the electromagnetic compatibility of medical devices. 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products> or from the Center for Biologics Evaluation and Research at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. This guidance document is also available at <https://www.regulations.gov> and at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Electromagnetic Compatibility (EMC) of Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please include the complete title and the document number 16040 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”.	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25306 Filed 11–16–20; 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 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://](http://www.hrsa.gov/vaccinecompensation/index.html)

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 October 1, 2020, through October 31, 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.

Thomas J. Engels,
Administrator.

List of Petitions Filed

1. Angela White, Memphis, Tennessee, Court of Federal Claims No: 20-1302V
2. Donna Battaglia, Westminster, Maryland, Court of Federal Claims No: 20-1303V
3. David Stibor on behalf of Estate of Yolanda Stibor, Deceased, Las Vegas, Nevada, Court of Federal Claims No: 20-1304V
4. Jennifer Sepate, Cold Spring, Kentucky, Court of Federal Claims No: 20-1305V
5. Miranda Anglim, Philadelphia, Pennsylvania, Court of Federal Claims No: 20-1309V
6. Megan Fetterman, Kansas City, Missouri, Court of Federal Claims No: 20-1310V
7. Dawson Langdon, Boston, Massachusetts, Court of Federal Claims No: 20-1311V
8. Anna Tracy, Boston, Massachusetts, Court of Federal Claims No: 20-1312V
9. Charles J. Keyser, Henderson, Nevada, Court of Federal Claims No: 20-1313V
10. Michelle Wylie, Enfield, Connecticut, Court of Federal Claims No: 20-1314V
11. Jim McTighe and Linda McTighe on behalf of J.M., Phoenix, Arizona, Court of Federal Claims No: 20-1316V
12. Lisa Hrica, Washington, District of Columbia, Court of Federal Claims No: 20-1317V
13. Ronald E. White, Charlotte, North Carolina, Court of Federal Claims No: 20-1319V
14. Latoya McCoy, Port Neches, Texas, Court of Federal Claims No: 20-1321V
15. Carolina Sanchez, Miami, Florida, Court of Federal Claims No: 20-1322V
16. Daniel Mauro, Castle Rock, Colorado, Court of Federal Claims No: 20-1326V
17. Brian Angelone, New York, New York, Court of Federal Claims No: 20-1327V
18. Thomas Roche, New York, New York, Court of Federal Claims No: 20-1328V
19. Karen Garrard, Travelers Rest, South Carolina, Court of Federal Claims No: 20-1331V
20. Drake Dixon, Tacoma, Washington, Court of Federal Claims No: 20-1332V
21. Vanessa Richardson, Birmingham, Alabama, Court of Federal Claims No: 20-1333V
22. Young Park, Washington, District of Columbia, Court of Federal Claims No: 20-1334V
23. Donna Maria Peterson, Atlanta, Georgia, Court of Federal Claims No: 20-1335V
24. Francis Zilinski, Boston, Massachusetts, Court of Federal Claims No: 20-1336V
25. Benita Turner on behalf of I.T., Phoenix, Arizona, Court of Federal Claims No: 20-1337V
26. Dianne Rice-Hansen, Bangor, Maine, Court of Federal Claims No: 20-1338V
27. Patricia Hertzog, Brownstown, Pennsylvania, Court of Federal Claims No: 20-1339V
28. Teresa Mazza, Rochester, New York, Court of Federal Claims No: 20-1340V
29. Megan Morey, Lebanon, New Hampshire, Court of Federal Claims No: 20-1341V
30. Christopher Jay Hankins, North Bend, Washington, Court of Federal Claims No: 20-1342V
31. Leroy Cantrell, San Antonio, Texas, Court of Federal Claims No: 20-1343V
32. Sarah Wells, Santa Cruz, California, Court of Federal Claims No: 20-1344V
33. Candace Harvey and Shawn Harvey on behalf of B.H., Boston, Massachusetts, Court of Federal Claims No: 20-1345V
34. Renee Majerus, Cleveland, Ohio, Court of Federal Claims No: 20-1346V
35. Elizabeth A. Adams, Salt Lake City, Utah, Court of Federal Claims No: 20-1347V
36. Javier O. Salazar, Waupun, Wisconsin, Court of Federal Claims No: 20-1348V
37. Leila Marie Beeby, Stillwater, Oklahoma, Court of Federal Claims No: 20-1349V

38. Gregory Monson, Anderson, California, Court of Federal Claims No: 20–1350V
39. Darlene Querio, Fenton, Michigan, Court of Federal Claims No: 20–1351V
40. Veronica Vogel, Pasadena, Texas, Court of Federal Claims No: 20–1352V
41. Suzanne Sullivan, Morristown, New Jersey, Court of Federal Claims No: 20–1353V
42. Tracy Wiggins, Raleigh, North Carolina, Court of Federal Claims No: 20–1354V
43. Raejean Zazzara, Sun City, Arizona, Court of Federal Claims No: 20–1355V
44. Diana Bunten, Blairsville, Georgia, Court of Federal Claims No: 20–1356V
45. Pamela DeZurik, Durham, North Carolina, Court of Federal Claims No: 20–1357V
46. Katherine Cummings and Jared Cummings on behalf of O.C., Newark, Ohio, Court of Federal Claims No: 20–1358V
47. Ashley Voag, Everett, Washington, Court of Federal Claims No: 20–1359V
48. Michael J. Diaz, Riverdale, Georgia, Court of Federal Claims No: 20–1360V
49. Raviteja Bodepudi, Irving, Texas, Court of Federal Claims No: 20–1361V
50. Daniel Proctor, Santa Rosa, California, Court of Federal Claims No: 20–1362V
51. Cindy Smith, Emmett, Idaho, Court of Federal Claims No: 20–1363V
52. Christina Gillespie, Jacksonville, North Carolina, Court of Federal Claims No: 20–1364V
53. Rachel Kellogg, Bellport, New York, Court of Federal Claims No: 20–1365V
54. Donna Knasel, Norristown, Pennsylvania, Court of Federal Claims No: 20–1366V
55. Paul Shuping on behalf of T.S., Salisbury, North Carolina, Court of Federal Claims No: 20–1367V
56. Montra Turner, Louisville, Kentucky, Court of Federal Claims No: 20–1368V
57. Trenell Parfait, Murfreesboro, Tennessee, Court of Federal Claims No: 20–1369V
58. Dallas Chapman, Clive, Iowa, Court of Federal Claims No: 20–1370V
59. Laura Shevlin, Stuart, Florida, Court of Federal Claims No: 20–1372V
60. Charity Frimpong, Frederick, Maryland, Court of Federal Claims No: 20–1373V
61. Jesse D. Krebs, Cleveland, Ohio, Court of Federal Claims No: 20–1374V
62. Robert Anthony Simeone, III on behalf of R.S., Savannah, Texas, Court of Federal Claims No: 20–1375V
63. Maurice Lewis and Susan Lewis on behalf of N.L., South Portland, Maine, Court of Federal Claims No: 20–1376V
64. Rivian Robinson, Boston, Massachusetts, Court of Federal Claims No: 20–1378V
65. Deborah Sands, Tacoma, Washington, Court of Federal Claims No: 20–1379V
66. Sandra Ruiz, Los Angeles, California, Court of Federal Claims No: 20–1380V
67. Edward Vallee, Lakeland, Florida, Court of Federal Claims No: 20–1381V
68. Jean Bub, Antigo, Wisconsin, Court of Federal Claims No: 20–1382V
69. Michelle Tverberg, St. Croix Falls, Wisconsin, Court of Federal Claims No: 20–1383V
70. Laura Hailey, New York, New York, Court of Federal Claims No: 20–1386V
71. Allen Vela on behalf of J.V., Glendale, Arizona, Court of Federal Claims No: 20–1387V
72. Carla Faraldo, Seattle, Washington, Court of Federal Claims No: 20–1389V
73. Taylor Osborne, Brockton, Massachusetts, Court of Federal Claims No: 20–1390V
74. Ben D. Shiriak, Tappahannock, Virginia, Court of Federal Claims No: 20–1391V
75. Patricia Hoover on behalf of L.H., Huntingtown, Maryland, Court of Federal Claims No: 20–1394V
76. Dinna Paulin, Victorville, California, Court of Federal Claims No: 20–1395V
77. Diane Blake, Phoenix, Arizona, Court of Federal Claims No: 20–1398V
78. Monika Clarke on behalf of F.C., Collegeville, Pennsylvania, Court of Federal Claims No: 20–1400V
79. Wendy Riva, New York, New York, Court of Federal Claims No: 20–1401V
80. Leticia Starr, Laguna Niguel, California, Court of Federal Claims No: 20–1402V
81. Michael Antkowiak, Buffalo, New York, Court of Federal Claims No: 20–1404V
82. William Efron, Saint Paul, Minnesota, Court of Federal Claims No: 20–1405V
83. Brandon Sauter, Slidell, Louisiana, Court of Federal Claims No: 20–1406V
84. Ken Wingerter and Shaun Wingerter on behalf of H.W., Marietta, Georgia, Court of Federal Claims No: 20–1408V
85. Shamir Ally, New York, New York, Court of Federal Claims No: 20–1409V
86. Martha Honeycutt on behalf of Estate of Raymond Cecil Honeycutt, Deceased, Burkesville, Kentucky, Court of Federal Claims No: 20–1410V
87. Jami Shanes, Cleveland, Ohio, Court of Federal Claims No: 20–1411V
88. Frank Reuther, Slidell, Louisiana, Court of Federal Claims No: 20–1412V
89. Thomas Tallett, Levittown, Pennsylvania, Court of Federal Claims No: 20–1413V
90. Wade Allen Martin, Reno, Nevada, Court of Federal Claims No: 20–1414V
91. Angela McFadden, Philadelphia, Pennsylvania, Court of Federal Claims No: 20–1415V
92. Mary A. Haley, Suffolk, Virginia, Court of Federal Claims No: 20–1418V
93. Joseph Loverde and Susan Loverde on behalf of K.L., Boston, Massachusetts, Court of Federal Claims No: 20–1419V
94. Anna Ricci, Phoenix, Arizona, Court of Federal Claims No: 20–1420V
95. Robert Jaegle, Peru, Illinois, Court of Federal Claims No: 20–1421V
96. Julia Gillman, Boston, Massachusetts, Court of Federal Claims No: 20–1422V
97. Buddy Kindle, Dallas, Texas, Court of Federal Claims No: 20–1423V
98. Kelli Hill, Groveport, Ohio, Court of Federal Claims No: 20–1424V
99. Frederick Hanstine, Boston, Massachusetts, Court of Federal Claims No: 20–1425V
100. John Jacobs, Flint, Michigan, Court of Federal Claims No: 20–1426V
101. Linda M. Ricker, Slidell, Louisiana, Court of Federal Claims No: 20–1428V
102. Leigh Ann Marshall, Mt. Juliet, Tennessee, Court of Federal Claims No: 20–1429V
103. Sandra Anzalone, Buffalo, New York, Court of Federal Claims No: 20–1430V
104. Russell DeVoe, West Allis, Wisconsin, Court of Federal Claims No: 20–1432V
105. Janice E. Mayer, Issaquah, Washington, Court of Federal Claims No: 20–1434V
106. Shari Gress, Madison, Wisconsin, Court of Federal Claims No: 20–1437V
107. Houston Osburn, Lancaster, California, Court of Federal Claims No: 20–1438V
108. Gwen Snodgrass and Andrew Snodgrass on behalf of A.M.S., San

- Diego, California, Court of Federal Claims No: 20–1439V
109. Richard Dennis Miszewski, West Allis, Wisconsin, Court of Federal Claims No: 20–1440V
110. Raiza Halpert and Moshe Halpert on behalf of J.H., Monroe, New York, Court of Federal Claims No: 20–1441V
111. Dominique Roberts, Albuquerque, New Mexico, Court of Federal Claims No: 20–1442V
112. Timothy Schwalbe, Milwaukee, Wisconsin, Court of Federal Claims No: 20–1445V
113. Jennifer Mire, Republic, Missouri, Court of Federal Claims No: 20–1449V
114. Douglas J. Hoos, Grand Island, Nebraska, Court of Federal Claims No: 20–1450V
115. Kathleen Runser, College Park, Maryland, Court of Federal Claims No: 20–1451V
116. Karen Valentine, Boston, Massachusetts, Court of Federal Claims No: 20–1453V
117. Peggy Lund, Minnetonka, Minnesota, Court of Federal Claims No: 20–1454V
118. Julia Hunt, Brooklyn, New York, Court of Federal Claims No: 20–1455V
119. Heather Hayes and Mark Hayes on behalf of A.H., Cincinnati, Ohio, Court of Federal Claims No: 20–1457V
120. Kathryn Becker, Boston, Massachusetts, Court of Federal Claims No: 20–1461V
121. Humberto Rodriguez, Stamford, Connecticut, Court of Federal Claims No: 20–1464V
122. Erma Lamb, Boston, Massachusetts, Court of Federal Claims No: 20–1465V
123. Jennifer Inscoe, Forest, Virginia, Court of Federal Claims No: 20–1466V
124. Paula DeBusk, Fayetteville, Arkansas, Court of Federal Claims No: 20–1470V
125. Nicole Fortney, Boston, Massachusetts, Court of Federal Claims No: 20–1471V
126. Michael Kochenderfer, Boston, Massachusetts, Court of Federal Claims No: 20–1472V
127. Julie Roubik on behalf of Estate of Thomas Roubik, Deceased, Holmen, Wisconsin, Court of Federal Claims No: 20–1473V
128. Debra Gadd, Sandusky, Ohio, Court of Federal Claims No: 20–1474V
129. Michael Mendoza on behalf of Christian Mendoza, Chino, California, Court of Federal Claims No: 20–1475V
130. Dianne Byrd, Albuquerque, New Mexico, Court of Federal Claims No: 20–1476V
131. Krista Wall, Encinitas, California, Court of Federal Claims No: 20–1477V
132. Grace Shain on behalf of H.S., Phoenix, Arizona, Court of Federal Claims No: 20–1478V
133. Angela Butts, Washington, District of Columbia, Court of Federal Claims No: 20–1479V
134. Melissa Manie, Moberly, Missouri, Court of Federal Claims No: 20–1482V
135. Carmen C. Salas, San Juan, Puerto Rico, Court of Federal Claims No: 20–1483V
136. Mitzi Lee, Richmond, Virginia, Court of Federal Claims No: 20–1484V
137. Kathryn DeLeon on behalf of N.C., Boston, Massachusetts, Court of Federal Claims No: 20–1485V
138. John Michael Dulaney, Boerne, Texas, Court of Federal Claims No: 20–1488V
139. Peggy McCarter, Greensboro, North Carolina, Court of Federal Claims No: 20–1490V
140. Francine Russo, Athens, Georgia, Court of Federal Claims No: 20–1491V
141. Kelli Wilson, Caldwell, Idaho, Court of Federal Claims No: 20–1492V
142. Melissa Greenberg and Richard Greenberg on behalf of M.G., Boston, Massachusetts, Court of Federal Claims No: 20–1493V
143. Nina Cupples, Rutherford, Tennessee, Court of Federal Claims No: 20–1494V
144. Rodney Burrill, Seattle, Washington, Court of Federal Claims No: 20–1495V
145. Veronica Williams, Dallas, Texas, Court of Federal Claims No: 20–1499V
146. Maria Ramos, The Woodlands, Texas, Court of Federal Claims No: 20–1500V
147. Audrey Chinnock, Overland Park, Kansas, Court of Federal Claims No: 20–1501V
148. Regina Mileouski, Dresher, Pennsylvania, Court of Federal Claims No: 20–1502V
149. Luis Rodriguez, Richmond, Virginia, Court of Federal Claims No: 20–1503V
150. Debra S. Colgan, White Plains, New York, Court of Federal Claims No: 20–1505V
151. Kathleen Finn, Boston, Massachusetts, Court of Federal Claims No: 20–1506V

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BILLING CODE 4165–15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information—Landscape Analysis To Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) in the Department of Health and Human Services, in partnership with other federal agencies, seeks to gain a more comprehensive understanding from health systems, community based organizations, academic institutions, non-federal government agencies, innovators, entrepreneurs, non-profit organizations, and other relevant stakeholders regarding innovative solutions to chronic disease management leveraging novel technologies (e.g., artificial intelligence (AI), biosensors, apps, remote monitoring, 5G) to optimize compliance with evidence-based standards of care in disease states that cause significant morbidity and mortality in aging populations in underserved areas (e.g., low income, Medicaid-eligible, rural). OASH will review information collected in this request for information (RFI) to better inform federal government priorities and programs. We also seek to identify opportunities to strengthen the U.S. healthcare system, as a whole, through public-private partnerships in data sharing, comprehensive analytics including AI, and other potential mechanisms. OASH welcomes public feedback related to how these questions should be addressed and/or potential solutions. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on December 22, 2020.

ADDRESSES: Individuals are encouraged to submit responses electronically to OASHcomments@hhs.gov. Please indicate “RFI RESPONSE” in the subject line of your email. Submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Respond concisely and in plain language. You may use any structure or layout that