animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For food and color additive products, the testing phase begins on the date a major health or environmental effects test is begun and runs until the approval phase begins. The approval phase begins on the date a petition relying on the major health or environmental effects test and requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) is initially submitted to FDA and ends upon whichever of the following occurs last: (i) The regulation for the additive becomes effective; or (ii) objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or (iii) proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a food and color additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA has approved for marketing the food additive ADVANTAME. ADVANTAME may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to achieve the intended technical effect, in foods for which standards of identity established under section 401 of the FD&C Act do not preclude such use. Subsequent to this approval, the USPTO received patent term restoration applications for ADVANTAME (U.S. Patent Nos. 6,548,096 and 7,141,263) from Ajinomoto Co., Inc., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated October 30, 2015, FDA advised the USPTO that this food and color additive had undergone a regulatory review period and that the approval of ADVANTAME represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ADVANTAME is 4,967 days. Of this time, 3,091 days occurred during the testing phase of the regulatory review period, while 1,876 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a major health or environmental effects test on the food additive was initiated: October 16, 2000. FDA has verified the Ajinomoto Co., Inc. claim that October 16, 2000, is the date the major health or environmental effects test was begun.

2. The date a petition relying on the major health or environmental effects test and requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Federal Food, Drug, and Cosmetic Act is initially submitted to FDA: April 2, 2009. The applicant claims that the food additive petition (FAP) for ADVANTAME (FAP 9A4778) was submitted on March 30, 2009. However, according to FDA records, FAP 9A4778 was submitted on April 2, 2009, when a complete application was received.

3. The date the regulation for the additive becomes effective or the date objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted, or the date proceedings resulting from objections to the regulation after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted: May 21, 2014.

FDA has verified the applicant’s claim that FAP 9A4778 became effective on May 21, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see DATES). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to https://www.regulations.gov at Docket No. FDA—2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,
Associate Commissioner for Policy.

[PR Doc. 2017–25780 Filed 11–29–17; 8:45 am]

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 Health and Human Services 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, Acting
Clerk, United States Court of Federal
Claims, 717 Madison Place NW.,
For information on HRSA’s role in the
Program, contact the Director, National
Vaccine Injury Compensation Program,
5600 Fishers Lane, Room 08N146B,
Rockville, MD 20857; (301) 443–6593,
or visit our Web site 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 U.S. Court of Federal Claims and to
serve a copy of the petition on 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, 2017, through October 31,
2017. This list provides the name of
petitioner, city and state of vaccination
(if known 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
   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 U.S. 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, MD
20857. The Court’s caption (Petitioner’s
Name v. Secretary of HHS) and the
administrative number of the case
are included. Each caption and
administrative number is followed by
the case number.
George Sigounas,
Administrator.

List of Petitions Filed
1. Connie Fong, San Mateo, California,
   Court of Federal Claims No: 17–
   1400V
2. Matthew McDermott, Babylon, New
   York, Court of Federal Claims No:
   17–1401V
3. Marcella Boettcher, Pittsburg, Kansas,
   Court of Federal Claims No: 17–
   1402V
4. Alice Rhee, San Antonio, Texas,
   Court of Federal Claims No: 17–
   1403V
5. Julie K. Buyers, Indianapolis, Indiana,
   Court of Federal Claims No: 17–
   1406V
6. Deborah Kay Tomlin, Richmond,
   Virginia, Court of Federal Claims
   No: 17–1410V
7. Debra Sepulveda, Portland, Maine,
   Court of Federal Claims No: 17–
   1412V
8. Cynthia Levin, Orange, Virginia,
   Court of Federal Claims No: 17–
   1413V
9. Charles Thompson, North Fort Myers,
   Florida, Court of Federal Claims No:
   17–1414V
10. Samuel Kazery, Fayetteville,
    Arkansas, Court of Federal Claims
    No: 17–1415V
11. Julie Nicholson, Lynchburg,
    Virginia, Court of Federal Claims
    No: 17–1416V
12. Keith Noe and Carol Langley on
    behalf of J. J. N., Brockton,
    Massachusetts, Court of Federal
    Claims No: 17–1418V
13. Mitchell Godfrey, Bozeman,
    Montana, Court of Federal Claims
    No: 17–1419V
14. Andrea Dule, Raleigh, North
    Carolina, Court of Federal Claims
    No: 17–1420V
15. Amy Capesius, Broomfield,
    Colorado, Court of Federal Claims
    No: 17–1421V
16. Wanda E. Evin, Fargo, North Dakota,
    Court of Federal Claims No: 17–
    1422V
17. Cindy Kissler, Milwaukee,
    Wisconsin, Court of Federal Claims
    No: 17–1423V
18. Lindsey Lally, San Francisco,
    California, Court of Federal Claims
    No: 17–1426V
19. Virginie Bridges, Charlotte, North
    Carolina, Court of Federal Claims
    No: 17–1427V
20. Scott A. Youngmark, Waupun,
    Wisconsin, Court of Federal Claims
    No: 17–1431V
21. Mary Tennesen, St. Louis, Missouri,
    Court of Federal Claims No: 17–
    1441V
22. Bita Fotuhi, Baltimore, Maryland,
    Court of Federal Claims No: 17–
    1442V
23. Samuel J. LaBine, St. Cloud,
    Minnesota, Court of Federal Claims
    No: 17–1443V
24. Michael Puilio, Staten Island, New
    York, Court of Federal Claims No:
    17–1444V
25. Paul Gallagher on behalf of R. G.,
    South Hadley, Massachusetts, Court
    of Federal Claims No: 17–1445V
27. Ginger Pahos, Minneapolis, Minnesota, Court of Federal Claims No: 17–1455V
28. April J. Barr, Nashville, Indiana, Court of Federal Claims No: 17–1462V
29. Genevieve Mergen-Barret, Coconut Creek, Florida, Court of Federal Claims No: 17–1469V
30. Robert Nemmer, Salt Lake City, Utah, Court of Federal Claims No: 17–1464V
31. Bangone Thirakul, San Diego, California, Court of Federal Claims No: 17–1465V
32. Sandra Sneathen, Charlevoix, Michigan, Court of Federal Claims No: 17–1466V
33. Leslee Moran, Fremont, New Hampshire, Court of Federal Claims No: 17–1467V
34. Purna Kami, Columbus, Ohio, Court of Federal Claims No: 17–1468V
35. Ramon Cuevas, Boston, Massachusetts, Court of Federal Claims No: 17–1469V
36. Rebecca Eugley, Oxford, Maine, Court of Federal Claims No: 17–1470V
37. Patricia Piazza, Brick, New Jersey, Court of Federal Claims No: 17–1471V
38. Olwen Dowling, Florence, Massachusetts, Court of Federal Claims No: 17–1472V
40. Lucita Singleton, Shelbyville, Tennessee, Court of Federal Claims No: 17–1474V
41. Katherine Kelly, Celebration, Florida, Court of Federal Claims No: 17–1475V
42. Deborah Miller on behalf of A. M., Ithaca, New York, Court of Federal Claims No: 17–1476V
43. Kathleen Mosley, Oklahoma City, Oklahoma, Court of Federal Claims No: 17–1477V
44. Sean McLoughlin on behalf of John McLoughlin, Summit, New Jersey, Court of Federal Claims No: 17–1478V
45. Angelina Cavallo and Matthew Polanco on behalf of M. P., Paterson, New Jersey, Court of Federal Claims No: 17–1479V
46. Frances MacCormack, Somerset, New Jersey, Court of Federal Claims No: 17–1480V
47. Bryan Kitt, West Bend, Wisconsin, Court of Federal Claims No: 17–1482V
49. Linda Jones, Springfield, Missouri, Court of Federal Claims No: 17–1486V
50. Hector Baez, Baxley, Georgia, Court of Federal Claims No: 17–1488V
51. Elmer J. George on behalf of James C. McMurtry, Lebanon, Kentucky, Court of Federal Claims No: 17–1489V
52. Damaris Shaffer Miltenberger, Carbondale, Illinois, Court of Federal Claims No: 17–1491V
53. Angela B. Cooper, Pittsburgh, Pennsylvania, Court of Federal Claims No: 17–1493V
54. Jessica Watts, Indianapolis, Indiana, Court of Federal Claims No: 17–1494V
55. Kevin R. Danchik, Pittsburgh, Pennsylvania, Court of Federal Claims No: 17–1495V
56. Jan Skugstad, Minneapolis, Minnesota, Court of Federal Claims No: 17–1497V
57. Laurie Ann Minns, Corvallis, Oregon, Court of Federal Claims No: 17–1499V
58. Marlena Carrillo on behalf of K. C., Phoenix, Arizona, Court of Federal Claims No: 17–1500V
59. Gary Foster, Conway, Arkansas, Court of Federal Claims No: 17–1502V
60. Clifford Schneider, Naples, Florida, Court of Federal Claims No: 17–1504V
61. Melba L. Callaway, Pittsburgh, Pennsylvania, Court of Federal Claims No: 17–1506V
62. Donald Jackson, Stafford, Virginia, Court of Federal Claims No: 17–1508V
63. Stephanie Walker, Poplar Bluff, Missouri, Court of Federal Claims No: 17–1509V
64. Karen Falconio, Langhorne, Pennsylvania, Court of Federal Claims No: 17–1510V
65. Robin Lara Camacho Keja, Harrisburg, Pennsylvania, Court of Federal Claims No: 17–1511V
66. Rafael D. Leal, Houston, Texas, Court of Federal Claims No: 17–1513V
67. Tawnya Montano, Murray, Utah, Court of Federal Claims No: 17–1526V
68. Ruth Nortey, Tulsa, Oklahoma, Court of Federal Claims No: 17–1527V
69. Ryan Thompson, Washington, District of Columbia, Court of Federal Claims No: 17–1529V
70. Ryan M. Schmidt, Ooltewah, Tennessee, Court of Federal Claims No: 17–1530V
71. Donna Wissbaum, Montello, Wisconsin, Court of Federal Claims No: 17–1531V
72. Latoya Christie on behalf of P. A., Wellesley Hills, Massachusetts, Court of Federal Claims No: 17–1532V
73. Connie Rainbolt, Torrington, Wyoming, Court of Federal Claims No: 17–1533V
74. John G. Rima, North Bend, Washington, Court of Federal Claims No: 17–1534V
75. Samantha Rivera and Timur Rivera on behalf of S. R., Beverly Hills, California, Court of Federal Claims No: 17–1535V
76. Stacy Hendrick, Hampton, Virginia, Court of Federal Claims No: 17–1536V
77. Sheila Harshaw, Van Nuys, California, Court of Federal Claims No: 17–1537V
78. Quinton Kapper, Greenwich, New York, Court of Federal Claims No: 17–1538V
79. Melani DePetro, Boston, Massachusetts, Court of Federal Claims No: 17–1539V
80. Paul L. Cooper, Arlington, Virginia, Court of Federal Claims No: 17–1541V
81. Shannon Mercer, Springboro, Ohio, Court of Federal Claims No: 17–1544V
82. Timothy Biery, Goodlettsville, Tennessee, Court of Federal Claims No: 17–1546V
83. Melanie Machado, Tacoma, Washington, Court of Federal Claims No: 17–1547V
84. Joyce Lineberger, Matthews, North Carolina, Court of Federal Claims No: 17–1548V
85. Suzanne Schaffer, San Diego, California, Court of Federal Claims No: 17–1550V
86. Robert David Dupach-Carron and Elizabeth Joanna Carron on behalf of A. R. D-C., Nassau, Bahamas, Court of Federal Claims No: 17–1551V
87. Audrey Walton, Bozeman, Montana, Court of Federal Claims No: 17–1552V
88. Clark Elaine, Salem, New Hampshire, Court of Federal Claims No: 17–1553V
89. Frances Labonte, Boston, Massachusetts, Court of Federal Claims No: 17–1554V
90. Robin Cooley, Louisville, Colorado, Court of Federal Claims No: 17–1556V
91. Cheyenne Whitesell on behalf of M. W., Deceased, Piermont, New York, Court of Federal Claims No: 17–1557V
92. Sarah D. Geschwindner, Concord, New Hampshire, Court of Federal Claims No: 17–1558V
SUMMARY: Reporting. The purpose of this notice is to take this opportunity to comment on the proposed information collection which requires 60 days for public comment. A copy of the OMB control number for this collection is available upon request from the address indicated. It is especially important that OMB receive your comments timely and therefore we have extended the Public Comment period to allow for a full 60 days.

ACTION: Notice and request for comment.

AGENCY: Indian Health Service, HHS.

Request for Public Comment: 60 Day Proposed Information Collection: Indian Health Service Information Security Ticketing and Incident Reporting

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–XXXX, titled, Information Security Ticketing and Incident Reporting. The purpose of this notice is to allow 60 days for public comment to be submitted directly to OMB. A copy of the OMB control number for this collection is available upon request from the address indicated.