

collection of information to OMB for review and clearance.

**Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species; 21 CFR Part 516 OMB Control Number 0910-0605—Extension**

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 (Pub. L. 108-282) amended the Federal Food, Drug, and Cosmetic Act to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are “MUMS-designated” by FDA. Minor use drugs are drugs for use in major species

(cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species; for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated reporting only applies to those sponsors who request and are subsequently granted “MUMS designation.”

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 (21 CFR 516.20) provides requirements on the content and format of a request for

MUMS-drug designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

*Description of Respondents:* The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of August 22, 2016 (81 FR 56658), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR Section   | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours  |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| 516.20; Content and format of MUMS request .....       | 15                    | 5                                  | 75                     | 16                          | 1,200        |
| 516.26; Requirements for amending MUMS designation ... | 3                     | 1                                  | 3                      | 2                           | 6            |
| 516.27; Change in sponsorship .....                    | 1                     | 1                                  | 1                      | 1                           | 1            |
| 516.29; Termination of MUMS designation .....          | 2                     | 1                                  | 2                      | 1                           | 2            |
| 516.30; Requirements of annual reports .....           | 15                    | 5                                  | 75                     | 2                           | 150          |
| 516.36; Insufficient quantities .....                  | 1                     | 1                                  | 1                      | 3                           | 3            |
| <b>Total</b> .....                                     |                       |                                    |                        |                             | <b>1,362</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: December 16, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**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 Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) 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 the Clerk, 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, 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 November 1, 2016, through November 30, 2016. 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 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 Health and Human Services) 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: December 15, 2016.

**James Macrae,**

*Acting Administrator.*

#### List of Petitions Filed

1. Linda Alvarez, Mankato, Minnesota, Court of Federal Claims No: 16-1438V.
2. Erika Reeder, Philadelphia, Pennsylvania, Court of Federal Claims No: 16-1439V.
3. Shelly Thompson, Wellesley, Massachusetts, Court of Federal Claims No: 16-1440V.
4. Wesley Dumas, Jacksonville, Florida, Court of Federal Claims No: 16-1441V.
5. Donna Huddy, Washington, District of Columbia, Court of Federal Claims No: 16-1442V.
6. Allen M. Horst, Goshen, Indiana, Court of Federal Claims No: 16-1443V.
7. Mary Jane Corn, Southport, North Carolina, Court of Federal Claims No: 16-1445V.
8. Indigo Grant on behalf of Mason Grant, White Plains, New York, Court of Federal Claims No: 16-1446V.
9. Kathleen Scarpato, York, Pennsylvania, Court of Federal Claims No: 16-1448V.
10. Mark Johnson, Dayton, Ohio, Court of Federal Claims No: 16-1449V.
11. Judith Isacoff, Arlington, Virginia, Court of Federal Claims No: 16-1450V.
12. Laurel Powell, Pocatello, Idaho, Court of Federal Claims No: 16-1452V.
13. Guy Irwin, Vienna, Virginia, Court of Federal Claims No: 16-1454V.
14. Patricia Barabas, Linwood, New Jersey, Court of Federal Claims No: 16-1455V.
15. Troy Duval, Greenville, Wisconsin, Court of Federal Claims No: 16-1456V.
16. Denise Goring, Chicago, Illinois, Court of Federal Claims No: 16-1458V.
17. Tommy Calhoun on behalf of Nancy Calhoun, Norwalk, Ohio, Court of Federal Claims No: 16-1459V.
18. Lance Antolick and Alyson Antolick on behalf of L. A., Huntsville, Alabama, Court of Federal Claims No: 16-1460V.
19. Gail Dirksen, Minot, North Dakota, Court of Federal Claims No: 16-1461V.
20. Eliseo Rael, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16-1462V.
21. Abby Dux, Boston, Massachusetts, Court of Federal Claims No: 16-1463V.
22. Gerald Temes, Louisville, Kentucky, Court of Federal Claims No: 16-1465V.
23. Stacy Ginn and Jennifer Ginn on behalf of R. G., Boston, Massachusetts, Court of Federal Claims No: 16-1466V.
24. Lindsay Hiatt, Templeton, California, Court of Federal Claims No: 16-1467V.
25. Susan Ross, White Plains, New York, Court of Federal Claims No: 16-1468V.
26. Mohammed K. Alam and Jannatul Mumtarina on behalf of T. M., New York, New York, Court of Federal Claims No: 16-1469V.
27. Candace Singer, Camp Hill, New York, Court of Federal Claims No: 16-1470V.
28. Staci Pohodich, Dallas, Texas, Court of Federal Claims No: 16-1471V.
29. Robert Wallace, Sandusky, Ohio, Court of Federal Claims No: 16-1472V.
30. Cynthia Cooper, Washington, District of Columbia, Court of Federal Claims No: 16-1476V.
31. Philip Ngo on behalf of Adrianna Ngo, Portland, Oregon, Court of Federal Claims No: 16-1478V.
32. Tamara Chavez on behalf of T. C., Piermont, New York, Court of Federal Claims No: 16-1479V.
33. Erin McLane, Bethlehem, Pennsylvania, Court of Federal Claims No: 16-1480V.
34. Stephanie Foster, Flowood, Mississippi, Court of Federal Claims No: 16-1484V.
35. Doreen Stewart on behalf of The Estate of Marie Cavallaro, Deceased, Cairo, New York, Court of Federal Claims No: 16-1486V.
36. Amanda Holder, Anniston, Alabama, Court of Federal Claims No: 16-1490V.
37. Patricia Walling, Nowata, Oklahoma, Court of Federal Claims No: 16-1493V.
38. Ebonie Weaver on behalf of T. M., Chicago, Illinois, Court of Federal Claims No: 16-1494V.
39. Brian Cassidy, Patchogue, New York, Court of Federal Claims No: 16-1495V.
40. Rachel Koenig, New York, New York, Court of Federal Claims No: 16-1496V.
41. Donna Mae Coneley, Spearfish, South Dakota, Court of Federal Claims No: 16-1497V.
42. Fredric Kerns, Boston, Massachusetts, Court of Federal Claims No: 16-1498V.
43. Patricia A. Spayde, Chesaning, Michigan, Court of Federal Claims No: 16-1499V.
44. Charles E. Sumner, Houston, Texas, Court of Federal Claims No: 16-1500V.
45. Darrell G. Mayo, Suffolk, Virginia, Court of Federal Claims No: 16-1502V.
46. Ginger Smith, Rochester, New York, Court of Federal Claims No: 16-1503V.
47. Anthony D. Maddox, Murfreesboro, Tennessee, Court of Federal Claims No: 16-1504V.

48. Omar M. Villarroel, Rockford, Illinois, Court of Federal Claims No: 16-1505V.
49. James F. Dunn, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16-1506V.
50. Jacquelynn Hernandez, Galveston, Texas, Court of Federal Claims No: 16-1508V.
51. Martha Shackelford, Houston, Texas, Court of Federal Claims No: 16-1509V.
52. Jenna Karakatsanis, Knoxville, Tennessee, Court of Federal Claims No: 16-1511V.
53. Arthur Zerbey, Boston, Massachusetts, Court of Federal Claims No: 16-1514V.
54. Carlos Barrantes-Vargas, Monmouth, New Jersey, Court of Federal Claims No: 16-1515V.
55. Bernadette Skorupska on behalf of N. S., New York, New York, Court of Federal Claims No: 16-1517V.
56. John Prater, Taylor, Michigan, Court of Federal Claims No: 16-1518V.
57. Scott Rodemoyer, North Canton, Ohio, Court of Federal Claims No: 16-1519V.
58. Renee Woods and Ryan Woods on behalf of T. W., Plano, Texas, Court of Federal Claims No: 16-1520V.
59. Jeanne Ivester, Cincinnati, Ohio, Court of Federal Claims No: 16-1522V.
60. Alla Goldman, Roseland, New Jersey, Court of Federal Claims No: 16-1523V.
61. Jamin Rader, Seattle, Washington, Court of Federal Claims No: 16-1524V.
62. Ariadna Nacianceno, Chapel Hill, North Carolina, Court of Federal Claims No: 16-1525V.
63. Janice Creighton, Richmond, California, Court of Federal Claims No: 16-1526V.
64. Rosalinda Vohs, San Antonio, Texas, Court of Federal Claims No: 16-1527V.
65. Glenda Garnsey, Georgetown, Delaware, Court of Federal Claims No: 16-1528V.
66. Joy Gilley, Burleson, Texas, Court of Federal Claims No: 16-1529V.
67. Crystal Adkins, Fredericksburg, Virginia, Court of Federal Claims No: 16-1530V.
68. Sharon Farnsworth, Garnett, Kansas, Court of Federal Claims No: 16-1531V.
69. Margaret R. Marsh, Clemmons, North Carolina, Court of Federal Claims No: 16-1532V.
70. Heather Ryan, Baton Rouge, Louisiana, Court of Federal Claims No: 16-1533V.
71. Christine Rogers, Mansfield, Ohio, Court of Federal Claims No: 16-1534V.
72. Edith Swensen, Clinton Park, New York, Court of Federal Claims No: 16-1535V.
73. Sheri Rocca, Cleveland, Ohio, Court of Federal Claims No: 16-1537V.
74. Raymond Fowler, Kennebunk, Maine, Court of Federal Claims No: 16-1538V.
75. Alan L. Hayward, Mason City, Iowa, Court of Federal Claims No: 16-1539V.
76. Dena McElerney and Patrick McElerney on behalf of C. M., Lithia, Florida, Court of Federal Claims No: 16-1540V.
77. Tina L. Eskelin, Beverly Hills, California, Court of Federal Claims No: 16-1543V.
78. David Novak, Chardon, Ohio, Court of Federal Claims No: 16-1544V.
79. Deborah B. Brown, Chapel Hill, North Carolina, Court of Federal Claims No: 16-1547V.
80. Kevin Kelly, Lebanon, Pennsylvania, Court of Federal Claims No: 16-1548V.
81. Kristi Marquardt, La Jolla, California, Court of Federal Claims No: 16-1551V.
82. Monica Portee, Columbia, South Carolina, Court of Federal Claims No: 16-1552V.
83. Claudia Cipowski, Munster, Indiana, Court of Federal Claims No: 16-1553V.
84. Lisa Barker, Jacksonville, Florida, Court of Federal Claims No: 16-1554V.
85. Linda Rees, Belton, Missouri, Court of Federal Claims No: 16-1555V.
86. Ashraf Mostafa, Towson, Maryland, Court of Federal Claims No: 16-1558V.
87. Dorothy Felix, Grand Rapids, Michigan, Court of Federal Claims No: 16-1560V.
88. Janice Sloan, Mt. Juliet, Tennessee, Court of Federal Claims No: 16-1561V.
89. Virginia Vahle, Lee, Massachusetts, Court of Federal Claims No: 16-1562V.
90. Valerie W. Alexander, Mankato, Minnesota, Court of Federal Claims No: 16-1563V.
91. Ron W. Flood, Spokane, Washington, Court of Federal Claims No: 16-1564V.
92. Eardeal Miller, Northport, Alabama, Court of Federal Claims No: 16-1566V.
93. Laura Winters, Wellesley Hills, Massachusetts, Court of Federal Claims No: 16-1570V.
94. Joseph J. Pass, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16-1572V.
95. Donald D. Dix, Lincoln, Nebraska, Court of Federal Claims No: 16-1574V.
96. Melissa Howie, Dublin, Ohio, Court of Federal Claims No: 16-1575V.
97. James Abdelnour, Fairhaven, Massachusetts, Court of Federal Claims No: 16-1580V.
98. Della Cantrell, Long Beach, California, Court of Federal Claims No: 16-1581V.
99. Christy Heil, Grove City, Ohio, Court of Federal Claims No: 16-1582V.
100. Betsy Graham, North Attleboro, Massachusetts, Court of Federal Claims No: 16-1583V.
101. Angelina Grujic, Boston, Massachusetts, Court of Federal Claims No: 16-1586V.
102. Michael Johnson, Boston, Massachusetts, Court of Federal Claims No: 16-1587V.
103. William Vanjura, Moberly, Missouri, Court of Federal Claims No: 16-1588V.
104. Claire Dunne, Chicago, Illinois, Court of Federal Claims No: 16-1590V.
105. Marc Howard, Fairhope, Alabama, Court of Federal Claims No: 16-1592V.
106. Timothy Krusemark, Granger, Indiana, Court of Federal Claims No: 16-1593V.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: 0990-0448-30D]

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990-0448, scheduled to expire on December 31, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before January 23, 2017.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-5683.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier 0990-0448-30D for reference.

*Information Collection Request Title:* Surgeon General's Pledge to End the Opioid Crisis.

*OMB No.:* 0990-0448.

*Abstract:* This information collection is a critical component of a campaign to encourage health care prescribers (the user) to take action in their clinical practice to reduce the number of prescription drug overdoses and reduce the likelihood of prescription opioid drugs ending up in the possession of those who may abuse them. This information collection involves obtaining user contact information, medical profession category, medical specialty, and responses to short questions specifically designed to provide anecdotal information and contextualize the impact of the prescription opioid epidemic.

*Need and Proposed Use of the Information:* This information collection serves to gather contact information from clinical prescribers and responses to two short answer questions describing how prescription opioid addiction has impacted their patients and/or their practice. Zip code, profession, and specialty will be collected and analyzed to present aggregate pledge data. Each element will also be utilized to send personalized campaign communication. Understanding the demographics of the medical practitioners will improve the efficacy of the campaign to end opioid