

“Total Sugars” declaration, we could exclude them from the “Total Sugars” declaration, or we could adjust the gram amount of the “Total Sugars” declaration based on their caloric contribution to the diet. What considerations could inform our approach? Please explain your reasoning, and provide data or other information that would support these considerations and any recommended approach.

2. In the guidance regarding allulose, we discuss factors that we considered when determining whether a sugar should be excluded from the declaration of “Total Sugars,” including pH of dental plaque after consumption, caloric value, and glycemic and insulinemic response. What, if any, other factors impact whether a sugar should be excluded from the declaration of “Total Sugars”? Please provide any data or other information that supports your response.

C. Declaration of Added Sugars

1. We could take one of various approaches to account for sugars that are metabolized differently than traditional sugars in the declaration of “Added Sugars.” For example, we could require them to be declared within the “Added Sugars” declaration, we could exclude them from the “Added Sugars” declaration, or we could adjust the gram amount of the “Added Sugars” or the %DV declaration based on their caloric contribution to the diet. What considerations could inform our approach? Please explain your reasoning, and provide data or other information that would support these considerations and any recommended approach.

2. In the guidance regarding allulose, we discuss factors that we considered when determining whether a sugar should be excluded from the declaration of “Added Sugars,” including caloric value and glycemic and insulinemic response. What other factors, if any, impact whether a sugar should be excluded from the declaration of “Added Sugars”? Please provide any data or other information that supports your response.

3. We might adjust the %DV for “Added Sugars” for the U.S. population 4 years of age and older based on the caloric contribution of the sugar. For example:

Assume a product contains 5 g of sucrose and 10 g of another sugar with a caloric value of 2 kcal/g per serving.

Step 1. Calculate the Total Caloric Contribution of Sugars (amount of sucrose (g/serving) × caloric value

(kcal/g)) + (amount of other sugar (g/serving) × caloric value (kcal/g))

- a. Sucrose: 5 g/serving × 4 kcal/g (caloric value of sucrose) = 20 kcal/serving
- b. Other sugar: 10 g/serving × 2 kcal/g (caloric value of other sugar) = 20 kcal/serving
- c. Total Caloric Contribution = 20 kcal/serving (sucrose) + 20 kcal/serving (other sugar) = 40 kcal/serving

- Step 2. Calculate Total Amount of Sugars Adjusted for the Total Caloric Contribution (Total Caloric Contribution of Sugars (kcal/serving) ÷ 4 kcal/g))
- Amount of Sugars Adjusted for Caloric Contribution = 40 kcal/serving ÷ 4 kcal/g = 10 g-equivalent/serving
- Step 3. Calculate %DV for Added Sugars (Amount of Sugars Adjusted for Caloric Contribution (g-equivalent) ÷ 50 g/day (DV for Added Sugars for the general U.S. population 4 years of age and older) × 100))
- $$\%DV = (10 \text{ g-equivalent} \div 50 \text{ g/day}) \times 100 = 20\%$$

What considerations are there with respect to adjusting the %DV declaration based on the caloric contribution of the sugar?

D. Label Declarations

1. We currently require the disclosure of sugar alcohols and sugars that are metabolized differently than traditional sugars in the ingredient statement in accordance with § 101.4(a), but also allow for the voluntary declaration of sugar alcohols on the Nutrition Facts label (§ 101.9(c)(6)(iv)). Please provide any data or other information that we could consider when determining whether we should allow for the voluntary declaration on the Nutrition Facts label of sugars that are metabolized differently than traditional sugars.

2. Sugar alcohols fall into a separate category of labeling and are excluded from the “Total Sugars” and “Added Sugars” declarations. Please provide any data or other information that we could consider when determining whether sugars that are metabolized differently than traditional sugars should be combined with sugar alcohols into one declaration within the Nutrition Facts label.

3. If sugars that are metabolized differently than traditional sugars are excluded from the “Total Sugars” and “Added Sugars” declarations and are combined with sugar alcohols in a separate labeling category within the Nutrition Facts label, what names

would be scientifically appropriate for such a category? Please provide any data or other information that supports your recommendation.

Dated: October 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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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 September 1, 2020, through September 30, 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. Kathleen Beldon, Sheffield, Ohio, Court of Federal Claims No: 20-1111V
2. Shanel Mayo, Chula Vista, California, Court of Federal Claims No: 20-1112V
3. Alison Guthrie, Little Rock, Arkansas, Court of Federal Claims No: 20-1113V
4. Troy Fontechia, Franklin, Tennessee, Court of Federal Claims No: 20-1114V
5. Christa Smith, Denver, Colorado, Court of Federal Claims No: 20-1115V
6. Lisa A. Whitehead, Cleveland, Tennessee, Court of Federal Claims No: 20-1118V
7. Darrell Williams, Louisville, Kentucky, Court of Federal Claims No: 20-1120V
8. Rebecca Jaramillo, Alexandria, Virginia, Court of Federal Claims No: 20-1122V
9. Amanda Baxter, Sacramento, California, Court of Federal Claims No: 20-1123V
10. John Simpson, Phoenix, Arizona, Court of Federal Claims No: 20-1124V
11. Amy Trudeau, Shelby Township, Michigan, Court of Federal Claims No: 20-1125V
12. Craig Divine on behalf of J.D., Phoenix, Arizona, Court of Federal Claims No: 20-1127V
13. Janet Smith, St. Louis, Missouri, Court of Federal Claims No: 20-1128V
14. Lindsey Austin, Asheville, North Carolina, Court of Federal Claims No: 20-1129V
15. Robert Laing, Deerfield, Illinois, Court of Federal Claims No: 20-1130V
16. Tonya Wilson, Fishers, Indiana, Court of Federal Claims No: 20-1131V
17. Quatina Battle, Nashville, North Carolina, Court of Federal Claims No: 20-1133V
18. Felicia A. Vinson, Racine, Wisconsin, Court of Federal Claims No: 20-1134V
19. Kelly Seim, Chicago, Illinois, Court of Federal Claims No: 20-1136V
20. Donna Burke, Salem, Wisconsin, Court of Federal Claims No: 20-1137V
21. Isabel Irizarry, Brooklyn, New York, Court of Federal Claims No: 20-1140V
22. Elizabeth Merwitz, Montgomery, Texas, Court of Federal Claims No: 20-1141V
23. Pamela Vitrano, New Orleans, Louisiana, Court of Federal Claims No: 20-1142V
24. Sara Storm and Joshua Storm on behalf of K.A.S., Madison, Wisconsin, Court of Federal Claims No: 20-1143V
25. Kathryn Frowein, Hartford, Wisconsin, Court of Federal Claims No: 20-1146V
26. Frederick Reno, Santa Rosa, California, Court of Federal Claims No: 20-1147V
27. Brett Van Leer-Greenberg on behalf of H. V.L., New York, New York, Court of Federal Claims No: 20-1150V
28. Sarah Hall, Lakeland, Florida, Court of Federal Claims No: 20-1151V
29. Sidney Lenox, Wichita, Kansas, Court of Federal Claims No: 20-1152V
30. Debbie Fresch, Fort Worth, Texas, Court of Federal Claims No: 20-1153V
31. Bernard Neuwirth on behalf of The Estate of Ellen C. Neuwirth, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20-1155V
32. Ronald Malinski, Sterling Heights, Michigan, Court of Federal Claims No: 20-1156V
33. Constantine Basdakis, Yorba Linda, California, Court of Federal Claims No: 20-1158V
34. Krystal Garcia, New York, New York, Court of Federal Claims No: 20-1159V
35. Deanna Ghormley, Bentonville, Arkansas, Court of Federal Claims No: 20-1161V
36. Ricki Lagozzino, Spokane, Washington, Court of Federal Claims No: 20-1162V
37. Emily Butcher, Boston, Massachusetts, Court of Federal Claims No: 20-1163V
38. Holly Reynolds, Brookings, Oregon, Court of Federal Claims No: 20-1165V
39. Patricia Horton, Cedar Rapids, Iowa, Court of Federal Claims No: 20-1166V
40. Holly Walls-Grom, Berkeley Heights, New Jersey, Court of Federal Claims No: 20-1167V
41. Donna E. Maestas, Rio Rancho, New Mexico, Court of Federal Claims No: 20-1168V
42. Dianne Needham, Scottsdale, Arizona, Court of Federal Claims No: 20-1169V
43. Kimberly Monk, Whitewater, Wisconsin, Court of Federal Claims No: 20-1171V
44. Derek Zobrist on behalf of Estate of Derek Edwin Zobrist, Deceased, Los Angeles, California, Court of Federal Claims No: 20-1172V
45. Lori Grady, Spokane, Washington, Court of Federal Claims No: 20-1175V
46. Kathleen Strycki, Gilbert, Arizona, Court of Federal Claims No: 20-1177V
47. Rebecca Cartwright, Wadsworth, Ohio, Court of Federal Claims No: 20-1178V
48. Jody Caldwell, Falconer, New York, Court of Federal Claims No: 20-1179V
49. Robert G. Wilson, Leesburg, Virginia, Court of Federal Claims No: 20-1181V
50. Jo Ann Pusich-Silas, Milton, Washington, Court of Federal Claims No: 20-1184V
51. Douglas Golden and Rishanne Dradt on behalf of Haleigh Golden, Deceased, Phoenix, Arizona, Court of Federal Claims No: 20-1186V
52. Kamille A. King, Murray, Utah, Court of

- Federal Claims No: 20–1187V
53. William A. Faith, Louisville, Kentucky, Court of Federal Claims No: 20–1188V
 54. Semeca Johnson, Chicago, Illinois, Court of Federal Claims No: 20–1189V
 55. Judith Adams, Grove City, Ohio, Court of Federal Claims No: 20–1190V
 56. Kenneth Heron, Arlington, Texas, Court of Federal Claims No: 20–1191V
 57. Anne Dowdle, Los Alamitos, California, Court of Federal Claims No: 20–1192V
 58. Nasser Abdulkadir, Houston, Texas, Court of Federal Claims No: 20–1193V
 59. Huong Thi Do, Philadelphia, Pennsylvania, Court of Federal Claims No: 20–1194V
 60. Donald Watford, Birmingham, Alabama, Court of Federal Claims No: 20–1195V
 61. Sara Campbell, New Orleans, Louisiana, Court of Federal Claims No: 20–1196V
 62. Jonathan Ruiz, New Haven, Connecticut, Court of Federal Claims No: 20–1198V
 63. Charlene Viets, Henderson, Kentucky, Court of Federal Claims No: 20–1199V
 64. Linda B. Haston, Ponte Vedra Beach, Florida, Court of Federal Claims No: 20–1200V
 65. James Gill, Fort Myers, Florida, Court of Federal Claims No: 20–1201V
 66. Vonnie Hatton, Bullhead City, Arizona, Court of Federal Claims No: 20–1202V
 67. Kyrian J. Marshall, Greenwood, Indiana, Court of Federal Claims No: 20–1203V
 68. Nora Anne Lawrence, Beaufort, North Carolina, Court of Federal Claims No: 20–1205V
 69. Marcia Roby, Hawesville, Kentucky, Court of Federal Claims No: 20–1206V
 70. Lindsay M. Camplin, Indianapolis, Indiana, Court of Federal Claims No: 20–1208V
 71. Patricia G. Hustead, Athens, Texas, Court of Federal Claims No: 20–1212V
 72. Casimir Chmielewski, Washington, District of Columbia, Court of Federal Claims No: 20–1213V
 73. Kristen McCormack, Chicago, Illinois, Court of Federal Claims No: 20–1214V
 74. Steven Bekker, Concord, North Carolina, Court of Federal Claims No: 20–1215V
 75. Angel Silveyra, Carol Stream, Illinois, Court of Federal Claims No: 20–1216V
 76. Robert Cameron, Boston, Massachusetts, Court of Federal Claims No: 20–1217V
 77. Maureen Reilly, Philadelphia, Pennsylvania, Court of Federal Claims No: 20–1218V
 78. Kimberly Asay, Salt Lake City, Utah, Court of Federal Claims No: 20–1219V
 79. Leslie Armstrong, Middletown, New York, Court of Federal Claims No: 20–1221V
 80. Randy Brouette, Palos Heights, Illinois, Court of Federal Claims No: 20–1222V
 81. Michael Calvin Miller, Commerce, Georgia, Court of Federal Claims No: 20–1225V
 82. Charlie Dee Mason, Greensboro, North Carolina, Court of Federal Claims No: 20–1226V
 83. Maureen Deighan, Hawthorne, New York, Court of Federal Claims No: 20–1227V
 84. Donna Verdisco, New Haven, Connecticut, Court of Federal Claims No: 20–1228V
 85. Christopher Cary, Scranton, Pennsylvania, Court of Federal Claims No: 20–1229V
 86. Sharlene Beal, Rockport, Maine, Court of Federal Claims No: 20–1232V
 87. Carl J. Dietz, New York, New York, Court of Federal Claims No: 20–1233V
 88. Kristin Cowan, Salt Lake City, Utah, Court of Federal Claims No: 20–1234V
 89. Jeanette Koka, Washington, District of Columbia, Court of Federal Claims No: 20–1235V
 90. Donna Proctor, Houston, Texas, Court of Federal Claims No: 20–1236V
 91. Melanie Fatone, Colchester, Connecticut, Court of Federal Claims No: 20–1238V
 92. Wilson V. Rivera, Rochester, New York, Court of Federal Claims No: 20–1239V
 93. Lenora Donlin, Forest Lake, Minnesota, Court of Federal Claims No: 20–1240V
 94. Jacqueline Brito, Norwalk, Connecticut, Court of Federal Claims No: 20–1241V
 95. Barbara Howard and Rodney Barnes on behalf of R.B., Mobile, Alabama, Court of Federal Claims No: 20–1242V
 96. Fettlework Norvell, Gaithersburg, Maryland, Court of Federal Claims No: 20–1243V
 97. James Marr, Fort Leonard Wood, Missouri, Court of Federal Claims No: 20–1244V
 98. Kara Couch, Frankfort, Kentucky, Court of Federal Claims No: 20–1246V
 99. Marika Yessa, Winfield, Illinois, Court of Federal Claims No: 20–1247V
 100. Anne Pisani on behalf of Estate of Frank Pisani, Deceased, Aston, Pennsylvania, Court of Federal Claims No: 20–1249V
 101. Angelea Buttles, Boston, Massachusetts, Court of Federal Claims No: 20–1250V
 102. Carol Steinhauer, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20–1251V
 103. Yasmin Sheriff, Chicago, Illinois, Court of Federal Claims No: 20–1252V
 104. Danielle Horne, Beverly, Massachusetts, Court of Federal Claims No: 20–1253V
 105. June T. Taylor and Edward Timothy Canavan on behalf of Estate of Edward T. Canavan, Deceased, Bay Shore, New York, Court of Federal Claims No: 20–1255V
 106. Anita Briant, Slidell, Louisiana, Court of Federal Claims No: 20–1257V
 107. Nichelle Williams, Boston, Massachusetts, Court of Federal Claims No: 20–1259V
 108. John Vandermeide, Newton, New Jersey, Court of Federal Claims No: 20–1260V
 109. Sarah Henderson, Union City, New Jersey, Court of Federal Claims No: 20–1261V
 110. Thomas Grant, San Antonio, Texas, Court of Federal Claims No: 20–1262V
 111. Elizabeth Holsworth, Jenkintown, Pennsylvania, Court of Federal Claims No: 20–1263V
 112. Sonya Elfar, Washington, District of Columbia, Court of Federal Claims No: 20–1264V
 113. Christopher DeMore, Durham, North Carolina, Court of Federal Claims No: 20–1265V
 114. Kaitlyn J. Reece on behalf of K.R., Manlius, New York, Court of Federal Claims No: 20–1267V
 115. Barbara Cerasuolo, Hudson, Massachusetts, Court of Federal Claims No: 20–1268V
 116. Robert Stern, New York, New York, Court of Federal Claims No: 20–1270V
 117. Robin Rossmann, Charlotte, North Carolina, Court of Federal Claims No: 20–1271V
 118. Blas Gutierrez on behalf of Gissell Gutierrez, Brentwood, New York, Court of Federal Claims No: 20–1273V
 119. Blas Gutierrez on behalf of Gissell Gutierrez, Brentwood, New York, Court of Federal Claims No: 20–1274V
 120. Julio Mendoza, Las Vegas, Nevada, Court of Federal Claims No: 20–1275V
 121. Beth A. Ross, Richmond, Virginia, Court of Federal Claims No: 20–1276V
 122. Kimberly Ruiz, Houston, Texas, Court of Federal Claims No: 20–1277V
 123. Sharon K. Dixon, Bloomington, Indiana, Court of Federal Claims No: 20–1278V
 124. Salina M. Flores, Crown Point, Indiana, Court of Federal Claims No: 20–1279V
 125. Mackenzie Summers, Phoenix, Arizona, Court of Federal Claims No: 20–1280V
 126. Larry J. Demas, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20–1281V
 127. Maryann Amicucci, Monongahela, Pennsylvania, Court of Federal Claims No: 20–1282V
 128. Bradley M. McLee, Sr. on behalf of Nadine Lynn McLee, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20–1283V
 129. Melissa Nicholson, Boston, Massachusetts, Court of Federal Claims No: 20–1284V
 130. Casey R. Morgan, Overland Park, Kansas, Court of Federal Claims No: 20–1286V
 131. Alex Brown, Boston, Massachusetts, Court of Federal Claims No: 20–1287V
 132. Matthew Miller, Boston, Massachusetts, Court of Federal Claims No: 20–1291V
 133. Jaclyn Godoy on behalf of L.G., White Plains, New York, Court of Federal Claims No: 20–1292V
 134. Alejandra Fajardo, Boston, Massachusetts, Court of Federal Claims No: 20–1294V
 135. Jyl Ann Poteet, Granbury, Texas, Court of Federal Claims No: 20–1295V
 136. Erica Nesteruk, Fort Mill, South Carolina, Court of Federal Claims No: 20–1297V
 137. Terisa A. Folaron, Shorewood, Wisconsin, Court of Federal Claims No: 20–1298V
 138. Eula Adeniji, Charlotte, North Carolina, Court of Federal Claims No: 20–1299V

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