

completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. Ask your financial institution about the fee and add it to your payment to ensure that your order is fully paid. Use the following account information when sending a wire transfer: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. (If needed, FDA's tax identification number is 53-0196965.)

*C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2017, or To Register a New Establishment for FY 2017*

Go to the Center for Devices and Radiological Health's Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm> and click the "Access Electronic Registration" link on the left side of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the "Access Electronic Registration" link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2016. Manufacturers of licensed biologics should register in the BER system at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/default.htm>.

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) or call 301-796-7400 for assistance. (**Note:** This email address and this telephone number are for assistance with establishment registration only; they are

not to be used for questions related to other aspects of medical device user fees.) Problems with BERS should be directed to <http://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm> or call 240-402-8360.

*D. Enter Your DFUF Order PIN and PCN*

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-17903 Filed 7-28-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1039]

#### General Wellness: Policy for Low Risk Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "General Wellness: Policy for Low Risk Devices." The guidance is intended to provide clarity to industry and FDA staff on Center for Devices and Radiological Health's (CDRH) compliance policy for low-risk products that promote a healthy lifestyle (general wellness products). By clarifying the policy on general wellness products, we hope to improve the predictability, consistency, and transparency on CDRH's regulation of these products. For purposes of the guidance, CDRH defines "general wellness products" as products which meet the following factors: They are intended for only general wellness use as defined in the guidance and present a low risk to the safety of users and other persons.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency

guidance documents are welcome at any time.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you wish to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2014-N-1039 for "General Wellness: Policy for Low Risk Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "General Wellness: Policy for Low Risk Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993-0002, 301-796-5528.

**SUPPLEMENTARY INFORMATION:**

## I. Background

CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of section 201(h) (21 U.S.C. 321(h)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or, if they are devices, whether they comply with the premarket review and postmarket regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: Registration and listing and premarket notification requirements (21 CFR part 807); labeling requirements (21 CFR part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR part 820); and Medical Device Reporting (MDR) requirements (21 CFR part 803).

For purposes of the guidance, CDRH defines "general wellness products" as products which meet the following factors: (1) Are intended for only general wellness use as defined in the guidance and (2) present a low risk to the safety of users and other persons. A general wellness product has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or has an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

CDRH's general wellness policy applies only to general wellness products that are low risk. In order to be considered low risk for purposes of the guidance, the product must not: (1) Be invasive, (2) be implanted, or (3) involve an intervention or technology that may pose risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure.

General wellness products may include exercise equipment, audio recordings, video games, software programs, and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the factors outlined in the guidance.

The FDA published in the **Federal Register** of January 20, 2015 (80 FR 2712), the notice of availability for the draft guidance entitled "General Wellness: Policy for Low Risk Devices; Draft Guidance for Industry and Food

and Drug Administration Staff" and the comment period for the guidance closed on April 20, 2015.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on General Wellness: Policy for Low Risk 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.

## III. Electronic Access

Persons interested in obtaining a copy of the 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "General Wellness: Policy for Low Risk Devices" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1300013 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807 (registration and listing and premarket notification (510(k))) have been approved under OMB control numbers 0910-0625 and 0910-0120, respectively; the collections of information in part 801 and § 809.10 (labeling) have been approved under OMB control number 0910-0485; the collections of information in part 820 (good manufacturing practice requirements as set forth in the quality system regulation) have been approved under OMB control number 0910-0073; and the collections of information in part 803 (MDR requirements) have been approved under OMB control number 0910-0437.

Dated: July 25, 2016.

**Leslie Kux,**

*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, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (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 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 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 Health and Human Services, 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 June 1, 2016, through June 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: July 22, 2016.

**James Macrae,**

*Acting Administrator.*

#### List of Petitions Filed

1. Ruby Lorenzo, Phoenix, Arizona, Court of Federal Claims No: 16-0647V.
2. Jacqueline Berg on behalf of Marilyn Moss, Deceased, Wellesley Hills, Massachusetts, Court of Federal Claims No: 16-0650V.
3. Sarah Etheridge-Criswell, Van Nuys, California, Court of Federal Claims No: 16-0652V.
4. Lisa Picker, St. Louis, Missouri, Court of Federal Claims No: 16-0654V.
5. Joann Brenner, Huntington Valley, Pennsylvania, Court of Federal Claims No: 16-0656V.
6. Talat Pervez, Long Island City, New York, Court of Federal Claims No: 16-0657V.
7. Gayle E. Gagne, Greenwood, Indiana, Court of Federal Claims No: 16-0660V.
8. Linda Ybarra, Dallas, Texas, Court of Federal Claims No: 16-0661V.
9. Stephen Capozzoli, Smithtown, New York, Court of Federal Claims No: 16-0666V.
10. Margaret Elledge, Carlsbad, California, Court of Federal Claims No: 16-0667V.
11. Nicholas Edwards, Fort Worth, Texas, Court of Federal Claims No: 16-0668V.
12. Christi Jewell, Jefferson, Ohio, Court of Federal Claims No: 16-0670V.
13. Luis C. Ramos, North Kansas City, Missouri, Court of Federal Claims No: 16-0673V.
14. Gregory Thompson, Philadelphia, Pennsylvania, Court of Federal Claims No: 16-0675V.
15. Fonda Bravo, Asheville, North Carolina, Court of Federal Claims No: 16-0679V.
16. Virginia A. Calfee, Christiansburg, Virginia, Court of Federal Claims No: 16-0680V.
17. Candy F. Hall, Linwood, New Jersey, Court of Federal Claims No: 16-0681V.
18. Hamid Ahmed, Dallas, Texas, Court of Federal Claims No: 16-0684V.
19. Marietta Schenck, Sarasota, Florida, Court of Federal Claims No: 16-0685V.