inflammatory drugs. It went into effect April 29, 2010.

Under that rule, the labeling for OTC IAAA products that contain acetaminophen and are labeled for adults only must include the liver warning described below. Similarly, the labeling for OTC IAAA products that contain acetaminophen and are labeled for adults and children under 12 year of age must include a similar liver warning described below.

Adults Only (§ 201.326(a)(1)(iii)(A) (21 CFR 201.326(a)(1)(iii)(A))):

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: ''for this product''] • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product.

Adults and children under 12 years of age (§ 201.326(a)(1)(v)(A) (21 CFR 201.326(a)(1)(v)(A))):

Liver warning: This product contains acetaminophen. Severe liver damage may occur if • adult takes more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: ''for this product''] • child takes more than 5 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product.

Although the currently proposed maximum daily dose of acetaminophen is 4,000 milligrams (mg), some OTC IAAA products that contain acetaminophen have directions for use that provide a maximum daily dose of acetaminophen for that product that is less than 4,000 mg. For example, for some OTC IAAA drug products that contain both acetaminophen and one or more other active ingredients, the maximum number of daily dosage units might be limited by an active ingredient other than acetaminophen, which could result in a maximum daily dose of acetaminophen that is less than 4,000 mg for that product. The optional statement, ''for this product,'' in the first bullet of the liver warning is intended to address these situations by clarifying that the maximum number of daily dosage units for a product might not reflect the maximum daily dose of acetaminophen.

However, the Agency understands that in certain circumstances, despite this optional statement, the wording of the first bullet in the warnings shown above might be interpreted as indicating that severe liver damage is associated with a total daily dose of acetaminophen that is less than 4,000 mg. This suggestion is not the intent of the regulation. To address this potential confusion, the Agency does not intend to object to the inclusion of a liver warning that differs from that required under § 201.326(a)(1)(iii)(A) and § 201.326(a)(1)(v)(A), provided the warning appears as described in the guidance.

In the **Federal Register** of July 5, 2012 (77 FR 39710), FDA published a draft guidance entitled ''Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Labeling for Products That Contain Acetaminophen.'' The July 2012 draft guidance gave interested persons an opportunity to submit comments through September 4, 2012. We have made changes to the guidance in response to comments received and have clarified the information in section III of the draft 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 Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Labeling for Products That Contain Acetaminophen. 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. Paperwork Reduction Act of 1965

The recommendations in this guidance are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29281 Filed 11–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that STRENSIQ (asfotase alfa), manufactured by Alexion Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6408, Silver Spring, MD 20993–0002, 301–796–4842, FAX: 301–796–9858, email: *larry.bauer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that STRENSIQ (asfotase alfa), manufactured by Alexion Pharmaceuticals, Inc., meets the criteria for a priority review voucher. Asfotase alfa is a long-term enzyme replacement therapy for patients with infantile- and juvenile-onset hypophosphatasia (HPP). HPP is a rare genetic disorder that affects the development of bones and teeth.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.*

For further information about STRENSIQ (asfotase alfa), go to the

Drugs@FDA Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29280 Filed 11–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice for Request for Nominations

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the National Advisory Council on Nurse Education and Practice (NACNEP). The NACNEP is in accordance with the provisions of 42 United States Code (U.S.C.) 297t; Section 851 of the Public Health Service Act, as amended. The Council is governed by provisions of Public Law 92–463, which sets forth standards for the formation and use of advisory committees.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be submitted to Regina Wilson, Advisory Council Operations, Bureau of Health Workforce, HRSA, 11w45c, 5600 Fishers Lane, Rockville, Maryland 20857. Mail delivery should be addressed to Regina Wilson, Advisory Council Operations, Bureau of Health Workforce, HRSA, at the above address, or via email to: *RWilson@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Fowler, Designated Federal Official, NACNEP, by phone at 301–443–7308 or by email at *efowler@hrsa.gov.* A copy of the current committee membership, charter and reports can be obtained by accessing the NACNEP Web site.

SUPPLEMENTARY INFORMATION: Under the authorities that established the NACNEP and the Federal Advisory Committee Act, HRSA is requesting nominations for new committee members. The NACNEP provides advice and recommendations to the Secretary and Congress in preparation of general regulations and concerning policy matters arising in the administration of Title VIII, including the range of issues relating to the nurse workforce, education, and practice improvement. Annually, the NACNEP prepares and submits to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the council, including findings and recommendations made by the NACNEP concerning the activities under Title VIII.

Specifically, HRSA is requesting nominations for voting members of the NACNEP representing leading authorities in the various fields of nursing, higher and secondary education, and associate degree schools of nursing; and from representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, and nurse anesthetists); from hospitals and other institutions and organizations which provide nursing services; from practicing professional nurses; from the general public; and full-time students enrolled in schools of nursing. The majority of NACNEP members shall be nurses.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. Nominations shall state that the nominee is willing to serve as a member of the NACNEP and appears to have no conflict of interest that would preclude the NACNEP membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the NACNEP to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of NACNEP), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted. Nominations will be considered as vacancies occur on the NACNEP. Nominations should be updated and resubmitted every 3 years to continue to be considered for committee vacancies.

HHS strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees. The Department also encourages geographic diversity in the composition of the committee. The Department encourages nominations of qualified candidates from all groups and locations. Appointment to the NACNEP shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–29195 Filed 11–16–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the National Advisory Council on Migrant (NACMH). The NACMH is authorized under 42 U.S.C. 218, section 217 of the Public Health Service (PHS) Act, as amended and governed by provisions of Public Law 92–463, as amended, (5 U.S.C. Appendix 2).

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be addressed to the Designated Federal Official, NACMH, Strategic Initiatives and Planning Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, Suite 17C–05, 5600 Fishers Lane, Rockville, Maryland 20857 or via email to: *JRodrigue@hrsa.gov* and *GCate@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: CDR Jacqueline Rodrigue, MSW, Designated Federal Official, NACMH, at (301) 443–1127 or email *JRodrigue@hrsa.gov.*

SUPPLEMENTARY INFORMATION: As authorized under section 330(g) of the Public Health Service Act, as amended, 42 U.S.C. 254b, the Secretary