requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.

This guidance applies to the subset of hearing aids that are regulated as class I air-conduction hearing aids under § 874.3300(b)(1) (21 CFR 874.3300(b)(1)) and class II wireless air-conduction hearing aids under § 874.3305, where hearing aid means ''any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing,'' as defined in § 801.420(a)(1). This guidance does not apply to class II bone-conduction hearing aids as identified in § 874.3300(b)(2). Also, hearing aids labeled for prescription use only, *e.g.,* those that are inserted deep in the ear canal by a hearing health professional, should continue to be sold only as directed.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115.(g)(2) (21 CFR 10.115(g)(2))). FDA believes that immediate implementation of the guidance is needed to assist in addressing a significant public health issue. Further, FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on conditions for sale for air-conduction hearing aids. 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 ''Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16041 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 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29724 Filed 12–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–1363]

Determination That SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (Sodium Chloride), Injectable, 234 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium chloride, injectable, 234 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–8767.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, is the subject of NDA 019329, held by Abraxis Pharmaceutical Products, and initially approved on April 22, 1987. SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER is indicated for use in patients who have special problems of sodium electrolyte intake or excretion, and for the treatment of sodium chloride and water deficiencies, which commonly occur in many diseases.

In a letter dated January 18, 1996, the original NDA holder, Fujisawa USA, Inc., notified FDA that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug

Product List'' section of the Orange Book.

Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated May 25, 2016 (Docket No. FDA–2016–P–1363), under 21 CFR 10.30, requesting that the Agency determine whether SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29674 Filed 12–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Vaccines—Amendment

ACTION: Notice of Amendment to the December 3, 2014, Declaration under the Public Readiness and Emergency Preparedness Act for Ebola Virus Disease Vaccines.

SUMMARY: The Secretary is amending the Declaration issued pursuant to section 319F–3 of the Public Health Service Act on December 3, 2014 (79 FR 73314) and amended on December 1, 2015 (80 FR 76541) to extend the effective time period for an additional 24 months and to clarify the description of Covered Countermeasures consistent with the terms of the Declaration and republishing the Declaration in its entirety as amended.

DATES: The Amended Declaration is effective as of December 3, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, through publication in the **Federal Register**, amend any portion of a Declaration. Using this authority, the Secretary is amending the Declaration that provides liability immunity to Covered Persons for activities related to the Covered Countermeasures, Ebola Virus Disease Vaccines listed in Section VI of the Declaration, to extend the effective time period for an additional 24 months and to clarify the description of Covered Countermeasures consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

The Ebola virus causes an acute, serious illness that is often fatal. From 2014 to 2015, West Africa experienced the largest and most complex Ebola outbreak since the virus was discovered in 1976, affecting populations in West African countries and travelers who left West Africa. In 2014, the World Health Organization (WHO) declared the Ebola Virus Disease Outbreak as a Public Health Emergency of International Concern under the framework of the International Health Regulations (2005). In March 2016, WHO determined that the Ebola outbreak no longer constituted a Public Health Emergency of International Concern, but emphasized the crucial need for continued support to prevent, detect and respond rapidly to any new Ebola outbreak in West Africa. Thus, there is a continuing need for development of vaccines against Ebola Virus Disease.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such