SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. Grantees are required by Congress to provide information for use in program monitoring and for Government Performance and Results Act (GPRA) purposes. This information collection reports the number of active volunteers, issues and inquiries received, other SMP program outreach activities, and the number of Medicare dollars recovered, among other SMP performance outcomes. This information is used as the primary method for monitoring the SMP Projects. ACL estimates the burden of this collection of information as follows: Respondents: 54 SMP grantees at 23 hours per month (276 hours per year, per grantee). Total Estimated Burden Hours: 7,452 hours per year.

Dated: May 25, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–12868 Filed 6–1–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Collaborating To Strengthen Food, Drug, and Medical Device Safety Systems; Notice of Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration (FDA) Philadelphia District Office, in co-sponsorship with the Association of Food and Drug Officials (AFDO), and the North Central Association of Food and Drug Officials, is announcing a conference entitled ''Collaborating to Strengthen Food, Drug, and Medical Device Safety Systems.'' This conference is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: The conference will be held on June 25 to June 29, 2016. See **SUPPLEMENTARY INFORMATION** for meeting times.

ADDRESSES: The Omni William Penn Hotel, 530 William Penn Pl., Pittsburgh, PA 15219. Attendees are responsible for their own accommodations.

FOR FURTHER INFORMATION CONTACT: Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., Suite 311, York, PA 17402, 717–757–2888, FAX: 717–650–3650, *ryoung@afdo.org.*

SUPPLEMENTARY INFORMATION: FDA has made education of the food, feed, drug, and device manufacturing community a high priority to help ensure the quality of FDA-regulated products. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information for stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government Agencies to small businesses.

The conference helps fulfill the U.S. Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include, but are not limited to the following:

- FDA Program Alignment
- Recalls from the Perspective of the District
- Inspection of Licensed Producers under the Marijuana for Medical Purposes Regulations (Health Canada)
- Foreign inspections
- Regulatory Intelligence
- FDA Inspections: Challenges and Opportunities (Working Luncheon)
- Drug Shortages
- Drug Supply Chain Act: Wholesale Drug Distributor and 3rd Party Logistics Provider
- Medical Device Single Audit Program
- Compliance Questions Panel

The Conference Web site is: *http://afdo.org/conference.* The meeting times are as follows:

Date	Meeting time
June 25	8 a.m. to 5 p.m.
June 26	8 a.m. to 6 p.m.
June 27	8 a.m. to 5:30 p.m.
June 28	8 a.m. to 5 p.m.
June 29	8 a.m. to 11:30 a.m.

Registration: The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited and registration will close after the course is filled; therefore, please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration; those accepted will receive confirmation. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the conference, beginning at 7:30 a.m. The cost of registration follows:

Category	Cost of registration
Member	$475
Non-Member	575
Additional Fee for Registration Postmarked After June 1, 2016	100

To register, please complete and submit an AFDO conference registration form, available at *http://pitt.afdo.org/registration.html,* along with a check, money order payable to ''AFDO''; the registrar will also accept Visa and MasterCard credit cards. Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., Suite 311, York, PA 17402. To register online, please visit *http://pitt.afdo.org/registration.html* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) For more information on the conference, or for questions about registration, please contact Randy Young (see **FOR FURTHER INFORMATION CONTACT**), email inquiries will also be accepted at *afdo@afdo.org,* or visit *http://www.afdo.org.*

If you need special accommodations due to a disability, please contact Randy Young (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12942 Filed 6–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–0378]

Determination That TRIVARIS (Triamcinolone Acetonide) Injectable Suspension, 80 Milligrams/Milliliters, 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 TRIVARIS (triamcinolone acetonide) injectable suspension, 80 milligrams/milliliters (mg/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 triamcinolone acetonide injectable suspension, 80 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 301–796–3977.

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.

TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, is the subject of NDA 22–220, held by Allergan, and initially approved on June 16, 2008. TRIVARIS is indicated for sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids. TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

The Weinberg Group submitted a citizen petition dated January 28, 2016 (Docket No. FDA–2016–P–0378), under 21 CFR 10.30, requesting that the Agency determine whether TRIVARIS (triamcinolone acetonide) injectable suspension, 80 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 TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TRIVARIS (triamcinolone acetonide) injectable suspension, 80 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 TRIVARIS (triamcinolone acetonide) injectable suspension, 80 mg/mL, 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: May 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12949 Filed 6–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0055]

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' The draft guidance, when finalized, will describe our views on voluntary short-term and long-term goals for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared. These goals are intended to address the excessive intake of sodium in the current population and promote improvements in public health.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on Issues 1 through 4 listed in section IV of this document by August 31, 2016. Submit either electronic or written comments on Issues 5 through 8 listed in section IV of this document by October 31, 2016.

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