

determined that TRIVARIS (triamcinolone acetonide) injectable suspension, 80 milligrams/milliliters (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.*

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**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

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 want 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-D-0055 for "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry." 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.

Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Kasey Heintz, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1376.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Introduction**

Many expert advisory panels have concluded that scientific evidence supports the value of reducing sodium intake in the general population (Ref. 1). Recent analysis, including the findings of the 2013 Institute of Medicine (IOM) report, "Sodium Intake in Populations: Assessment of Evidence" (IOM report), continue to support this conclusion (Ref. 2). The 2013 IOM report confirmed a positive relationship between higher levels of sodium intake and the risk of heart disease, and found substantial evidence of population benefit and no evidence of negative health effects associated with reductions in sodium intake down to 2,300 milligrams of

sodium per day (mg/day) (Ref. 2). Members of the committee which authored the 2013 IOM report also clarified in a subsequent publication that different groups using a variety of methods and data have obtained results consistent with the committee's analysis that current U.S. intake is excessive, that it should be reduced, and that reduction is expected to have significant public health benefit (Ref. 3). Moreover, the 2015 Dietary Guidelines Advisory Committee Sodium Working Group examined the relationship between sodium and blood pressure and other cardiovascular outcomes in adults, as well as sodium and blood pressure in children. The Committee's recommendations concurred with previous reports that sodium intake among the U.S. population remains high and that higher levels of sodium intake are associated with increased blood pressure and risk of cardiovascular disease (Ref. 4).

Multiple researchers have estimated the public health benefits associated with broad reduction in sodium intakes in the United States (Ref. 1). Reasonable reductions in average intake (modeled at a variety of intake levels below current intake, down to an average level of roughly 2,200 mg/day) have been estimated to result in tens of thousands fewer cases of heart disease and stroke each year, as well as billions of dollars in health care savings over time. A recent study (Ref. 5) used three epidemiological datasets to forecast the separate public health benefits of reducing the population's average sodium intake to 2,200 mg/day over 10 years. (This 2,200 mg/day final mean intake level was derived from intake values embedded in the sources of evidence used for the study.) Researchers found that this pattern of reduction would save between 280,000 and 500,000 premature deaths over 10 years; sustained sodium reduction would prevent additional premature deaths.

FDA is not conducting rulemaking with regard to sodium, and these goals are voluntary. Given the potentially significant benefits to public health, as well as FDA's role in safeguarding America's food supply and enabling consumers to choose healthy diets, we are committed to exploring effective and efficient strategies to promote sodium reduction in the food supply. We believe that these voluntary goals can be an effective means to achieve significant benefits to public health through sodium reduction in commercially processed, packaged, and prepared foods.

## II. Background

We are announcing the availability of a draft guidance for industry entitled “Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.” (For purposes of this draft guidance, “commercially processed, packaged, and prepared foods” refers to processed, multiple-ingredient foods that have been packaged by a member of the food industry for direct sale to consumers or for use in restaurants and similar retail food establishments including, but not limited to, restaurants, or for resale to other members of the food industry, as well as foods that are prepared by food establishments for direct consumption.) The draft guidance provides information to the food industry on sodium reduction, expressed as measurable voluntary goals for sodium content (from sodium chloride, commonly called “salt,” as well as other sodium-containing ingredients) in commercially processed, packaged, and prepared foods. Approximately 75 percent of sodium consumed by Americans is added to foods before they are sold (Ref. 6). Thus, the goals are intended to promote reductions in the amount of sodium added during processing, manufacturing, and preparation, especially for uses not necessary for microbial safety, stability, and/or physical integrity. We particularly encourage attention by food manufacturers whose products make up a significant proportion of national sales in one or more categories and restaurant chains that are national or regional in scope.

Broad adoption of these voluntary recommendations by the industry members would create a meaningful reduction in population intake over time and support adjustment of consumer taste preferences. We recognize that many companies have initiated sodium reduction efforts and have made commitments on their own. The voluntary goals are intended to support ongoing efforts, including progress that has already been made by industry. This approach also builds on other efforts such as an initiative by New York City in partnership with local and State health departments and health organizations and international approaches from foreign governments such as Canada and the United Kingdom. The voluntary goals are intended to provide a shared framework for describing and analyzing the success of voluntary reduction efforts by various industry stakeholders and to promote

continued discussion on sodium reduction opportunities. The guidance is intended to help achieve public health goals and see safe, gradual, and broadly distributed change over time across the full range of commercially processed, packaged, and prepared foods. To accomplish these goals, discussion and collaboration among FDA, Federal partners, the food industry, consumers, and other stakeholders will be essential.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You may use an alternate approach to reducing sodium as long as these approaches satisfy the requirements of the applicable statutes and regulations.

The draft guidance provides our tentative views with respect to identifying challenging, yet feasible, target mean and upper bound concentrations of sodium (referred to in this document as “sodium concentration goals”) across a wide variety of food categories. Our targets are based on our analysis of the current minimum and upper bound levels of sodium in a variety of identified food categories, available literature on the amount of salt needed for different functions in food, and discussions with experts on different food categories. Our milestone date for the short-term goals is the second year after publication of the final guidance. Our milestone date for the long-term goals is the 10th year after publication of the final guidance. The short-term targets are intended to be more easily achievable and as many as half of all products may already have achieved these interim targets. We recognize that the longer term targets are more difficult to achieve. We are aware that new ingredients capable of replacing some salt as well as other innovative strategies are being explored and more research and development may be needed. We also want to make clear that broader public health goals and maintenance of nutritional quality are important considerations in developing sodium reduction or reformulation strategies. For example, sodium reduction that relies on increases in added sugars would not be consistent with the public health goals of this guidance.

The sodium concentration goals in this voluntary draft guidance are intended to:

- Support increased food choice for consumers seeking to consume a diverse

diet that is consistent with recommendations of the 2015–2020 Dietary Guidelines for Americans;

- support the 2015–2020 Dietary Guidelines and the Healthy People 2020 recommendations of less than 2,300 mg per day for many individuals;
- provide shared goals as metrics (mg/100g) for voluntary reduction efforts by various industry stakeholders;
- support successful efforts already underway in the private sector to reduce sodium content;
- focus on total amount of sodium in a given food as opposed to any individual sodium-containing ingredient; and
- support and extend industry’s voluntary efforts to reduce sodium across the range of commercially processed, packaged, and prepared foods.

This guidance does not:

- Recommend specific methods and technologies for sodium reduction;
  - prescribe how much of any individual sodium-containing ingredient, such as salt or sodium nitrite, should be used in a formulation (in other words, we focus on the total amount of sodium in a given food);
  - focus on foods that contain only naturally occurring sodium (e.g., milk);
- or
- address salt that individuals add to their food.

As described in the notice “Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information” (76 FR 57050, September 15, 2011, referred to in this document as the 2011 request for comment), current sodium intake is substantially higher than what scientific and public health agencies and organizations have recommended in recent years. There have been a number of public and industry initiatives to reduce sodium intake, as well as initiatives in other countries (76 FR 57050 at 75051). In April 2010, IOM released a report titled “Strategies to Reduce Sodium Intake in the United States” which concluded that sodium intake, with the greatest contribution from salt, remains well above recommended levels (Ref. 1).

We recognize that a successful effort to reduce sodium intake requires information on a wide variety of topics, resulting from a genuine dialogue with all interested persons. To begin this dialogue, in 2011, FDA and the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) opened parallel dockets for public comment and described the rationale for sodium intake reduction and identified 15 specific issues for

comment by all interested persons (76 FR 57050). These issues concerned multiple aspects of sodium reduction, including technical challenges and opportunities, implementation of reduction targets, and potential unintended consequences of reduction.

In November 2011, FDA and FSIS, in conjunction with other Federal agencies interested in sodium reduction efforts, including the Centers for Disease Control and Prevention and USDA's Agricultural Research Service and Center for Nutrition Policy and Promotion, sponsored a public meeting to provide a forum for discussion of the issues raised in the 2011 request for comment. FDA and FSIS together received approximately 1,500 comments, which addressed the following key themes:

- The need for slow and gradual change;
- the importance of acknowledging technical and regulatory constraints;
- the need for consumer acceptance and market viability of new or reformulated products;
- the critical importance of maintaining a safe food supply;
- the potential health consequences of broad sodium reduction;
- the costs associated with broad reductions in sodium;
- the potential for positive incentives to promote reformulation; and
- reports of successful reduction efforts.

We reviewed the comments submitted to the 2011 request for comments as well as other available information. In particular, we have considered the 2013 IOM report, "Sodium Intake in Populations: Assessment of Evidence." The IOM report concluded that evidence from studies on direct health outcomes associated with sodium intake was sufficient to support reducing excessive sodium intake, noting a benefit for cardiovascular disease outcomes if population sodium intake came down to a level of 2,300 mg/day. Ultimately, this report reaffirmed the association between sodium intake and health outcomes, which supports the need to engage in population-based efforts to lower excessive dietary sodium intakes (Ref. 2).

### III. Paperwork Reduction Act of 1995

This draft 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 101 have

been approved under OMB control number 0910–0381. The collections of information in 21 CFR 101.11 have been approved under OMB control number 0910–0783.

### IV. Issues for Consideration

We developed the sodium targets using the best available representation of sodium in the food supply, based on product nutrition data from manufacturers and widely used sales data. We welcome comment on any issues related to the methods for developing the sodium targets and for implementation of this guidance. In particular, we are interested in comments on collecting and organizing these data into food categories, our methods for quantifying sodium content, refinements to the specific mean and upper bound targets based on adjustments of our category structures and data, and any challenges of implementing the voluntary goals. Please provide the reasoning behind your comments, including, where available, any data you may have.

1. Are there categories where foods have been grouped together that should be separated on the basis of different manufacturing methods or technical effects relating to the potential for sodium reduction? Conversely, are there categories which could be merged due to similar sodium functionality and potential for reduction? Are there foods that contribute to sodium intake that we have not effectively captured? Are the categories amenable for use by restaurant chains and if not, how should they be modified to make them amenable for use by restaurant chains?

2. Are the baseline sodium concentration values reasonably representative of the state of the food supply in 2010? For categories that do not appear representative, what food products are not adequately represented? Are there situations in which our method of quantification could lead to unrepresentative baseline values?

3. Are there categories for which the 2-year target concentration goals are infeasible? If so, why are these targets not feasible, *e.g.*, for technical reasons? What goals would be feasible in the short-term (2-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, "Target Development Example: Supplementary Memorandum to the Draft Guidance" (Ref. 7).

4. Are the short-term (2-year) timeframes for these goals achievable? If the timeframes are not achievable, what

timeframes would be challenging, but still achievable?

5. Are there categories for which the 10-year target concentration goals are infeasible? If so, why are these targets not feasible, *e.g.*, for technical reasons? What goals would be feasible in the long-term (10-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, "Target Development Example: Supplementary Memorandum to the Draft Guidance" (Ref. 7).

6. Are the long-term (10-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?

7. What specific research needs or technological advances (if any) could enhance the food industry's ability to meet these goals? What are possible innovations in the area of sodium reduction and are there any unintended consequences associated with their use?

8. What amendments to FDA's standard of identity regulations in 21 CFR parts 130–169 are needed to facilitate sodium reduction by permitting alternative ingredients to be used in standardized foods? For example, amendments could include revisions to specific standards (*e.g.*, cheese or cheese products) and to the general requirements for foods named by use of a nutrient content claim (*e.g.*, "reduced sodium") and a standardized term under 21 CFR 130.10.

### V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances>, or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

### VI. References

The following references are on display in FDA's Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

1. IOM. "Strategies to Reduce Sodium Intake in the United States," Washington DC: The National Academies Press (2010).

2. IOM. "Sodium Intake in Populations: Assessment of Evidence Institutes of

Medicine (IOM) Report,” Washington DC: The National Academies Press (2013).

3. Strom, B. L., C. A. M. Anderson, and J. H. Ix. “Sodium Reduction in Populations: Insights From the Institute of Medicine Committee.” *Journal of the American Medical Association*. July 3, 2013; 310(1): 31–32.

4. “Scientific Report of the 2015 Dietary Guidelines Advisory Committee,” Part B, Chapter 6. <http://www.health.gov/dietaryguidelines/2015-scientific-report/>. Accessed March 9, 2015.

5. Coxson, P. G., N. R. Cook, M. Joffres, Y. Hong, et al. “Mortality Benefits From U.S. Population-Wide Reduction in Sodium Consumption.” *Hypertension*. March 2013; 61:564–570.

6. Mattes, R. D. and D. Donnelly. “Relative Constitutions of Dietary Sodium Sources.” *Journal of the American College of Nutrition*. August 1991;10(4):383–93.

7. FDA. “Memo: Target Development Example: Supplementary Memorandum to the Draft Guidance (2016).”

Dated: May 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–12950 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–2013–D–1543]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Nonproprietary Naming of Biological Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 5, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–NEW and title “Nonproprietary Naming of

Biological Products.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance for Industry on Nonproprietary Naming of Biological Products OMB Control Number 0910–NEW

The guidance entitled “Guidance for Industry on Nonproprietary Naming of Biological Products” describes FDA’s current thinking on the need for biological products licensed under the Public Health Service Act (PHS Act) to bear a nonproprietary name that includes an FDA-designated suffix. There is a need to clearly identify biological products to facilitate pharmacovigilance and, for the purposes of safe use, to minimize inadvertent substitution. Accordingly, for biological products licensed under the PHS Act, FDA intends to designate a nonproprietary name that includes a core name and a distinguishing suffix. This naming convention is applicable to biological products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act (42 U.S.C. 262(a) or 262(k)).

The guidance includes information collection by requesting that applicants propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the proper name designated by FDA at the time of licensure for biological products licensed under the PHS Act. The suffix will be incorporated in the nonproprietary name of the product. The guidance recommends that applicants should submit up to 10 proposed suffixes, in the order of the applicant’s preference. We also recommend including supporting analyses demonstrating that the proposed suffixes meet the factors described in the guidance for FDA’s consideration.

As indicated in table 1, we estimate that we will receive a total of 40 requests annually for the proposed proper name for biological products submitted under section 351(a) of the PHS Act, and 6 requests annually for the proposed proper name for biosimilar products and interchangeable products

submitted under section 351(k) of the PHS Act. The average burden per response (hours) is based on our experience with similar information collection requirements for applicants to create and submit suffix proposals to FDA and in consideration of comments received in response to our 60-day notice.

In the **Federal Register** of August 28, 2015 (80 FR 52296), we published a 60-day notice requesting public comment on the proposed collection of information. Most comments supported our proposal to designate a suffix. Many comments suggested that a meaningful, distinguishable suffix may help to improve pharmacovigilance, enhance safety, and facilitate identification between biological products. Some comments supported use of a random suffix to avoid creating an unfair advantage for specific manufacturers. Several comments stated that the current practices of FDA and non-FDA entities for identifying biosimilar and interchangeable products is sufficient for the purpose of pharmacovigilance, and designation of a suffix is not needed. One comment stated that FDA’s estimate of 6 hours to submit proposed suffixes is based only on the time needed to prepare the submission itself after the multiple suffixes have been selected. The comment further stated that because FDA suggests that each respondent submit three suggested suffixes for consideration, the time needed to do an analysis of each suffix would exceed 720 hours per suffix (based on their own company experience) or 2,160 hours total for the three suffixes.

In response to the comments we note that our estimated annual reporting burden results from information that would be submitted to us by applicants in order to facilitate Agency designation of a suffix as part of the proper name of a biological product. We estimated that sponsors would spend 2 hours completing the submission for each of the three suffixes, resulting in 6 hours as the average burden. This estimate is an annualized figure based on the average number of responses per respondent and the average burden per response over a 3-year period. We understand that there is a certain amount of research and other costs that an applicant might encounter in analyzing any proposed name for a biological product. We also recognize that the burden may be higher for some applicants and lower for other applicants based on a variety of factors specific to the applicant.

The comment suggesting that it will take 720 hours to complete an analysis