Community Living (ACL) is announcing an opportunity to comment on the proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 30 days for public comment in response to the notice. This notice collects comments on the information collection requirements relating to an existing collection: Protection and Advocacy for Assistive Technology (PAAT) Program Performance Report (0985–0046).

DATES: Submit written comments on the collection of information by September 28, 2015.

ADDRESSES: Submit written comments on the collection of information by email to by fax 202–395–5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Clare Barnett, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4204, Washington, DC 20201, 202–357–3426.

SUPPLEMENTARY INFORMATION: Federal statute requires the Protection and Advocacy (P&A) System in each State to annually prepare and submit to the Secretary a report that includes documentation of the progress made. AIDD reviews the program performance report (PPR) for compliance and for program outcomes. AIDD will aggregate the information in the PPRs into a national profile of programmatic activities and accomplishments, and permit AIDD to track accomplishments against goals and formulate areas of technical assistance and compliance with Federal requirements.

ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PADD SGP	57	1	16	912

Estimated Total Annual Burden Hours: 912.

Dated: August 25, 2015.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2015–21409 Filed 8–27–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1543]

Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a draft guidance for industry entitled ''Nonproprietary Naming of Biological Products.'' The draft guidance describes our 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. Our current thinking is that shared nonproprietary names are not appropriate for all biological products. There is a need to clearly identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. Accordingly, for biological products, we intend to designate a nonproprietary name that includes a suffix composed of four lowercase letters. Each suffix will be incorporated in the nonproprietary name of the product. This naming convention is applicable to biological products previously licensed and newly licensed under the PHS Act. The nonproprietary name designated for originator biological products, related biological products, and biosimilars will include a unique suffix. However, FDA is considering whether the nonproprietary name for an interchangeable product should include a unique suffix, or should share the same suffix as its reference product. FDA invites comment on the draft guidance and solicits comments on ways to improve active pharmacovigilance systems for the purposes of monitoring the safety of biological products.

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 this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance, including responses to the questions in this notice, by October 27, 2015. Submit either electronic or written comments on the collection of information by October 27, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonproprietary Naming of Biological Products.'' The draft guidance describes our current thinking on the need for biological products licensed under section 351(a) or 351(k) of the PHS Act (42 U.S.C. 262(a) or 262(k)), as added by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act),[1] to bear a nonproprietary name that includes an FDA-designated suffix. Our current thinking is that shared nonproprietary names are not appropriate for all biological products. There is a need to clearly identify biological products for the purpose of pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. Accordingly, for biological products, we intend to designate a nonproprietary name that includes a suffix composed of four lowercase letters. Each suffix will be incorporated in the nonproprietary name of the product. This naming convention is applicable to biological products previously licensed and newly licensed under sections 351(a) and 351(k) of the PHS Act. The nonproprietary name designated for originator biological products, related biological products, and biosimilar products will include a unique suffix. However, as discussed in section IV.C. of the guidance, FDA is seeking comment on whether the nonproprietary name for an interchangeable product should include a unique suffix, or should share the same suffix as its reference product.

By differentiating biological products from one another that have not been determined by the FDA to be interchangeable, this naming convention is intended to help minimize inadvertent substitution. Inadvertent substitution may lead to unintended alternating or switching of biological products that have not been determined by FDA to be interchangeable. A naming convention that differentiates among biological products also could help facilitate pharmacovigilance for all biological products. By applying this naming convention to all biological products, this approach is intended to: (1) Encourage routine use of designated suffixes in ordering, prescribing, dispensing, and recordkeeping practices and (2) avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathways.

The draft guidance provides information to industry, the health care community, other regulatory agencies, and the public on our rationale for this naming convention. The draft guidance also is intended to assist applicants and application holders in proposing the suffix to be used as part of a biological product's nonproprietary name. The nonproprietary name designated by FDA in the license for a biological product licensed under the PHS Act is its ''proper name,'' and the term ''proper name'' is used throughout the draft guidance (see section 351(a)(1)(B)(i) of the PHS Act and 21 CFR 600.3(k)).

We invite comment on the draft guidance, including potential approaches for designating and incorporating suffixes retrospectively and prospectively into the nonproprietary names of all biological products. We also solicit comments on ways to improve active pharmacovigilance systems for the purposes of monitoring the safety of biological products. In providing comments, please consider the following:

1. What are the potential benefits and challenges of designating a suffix in the proper name of a biological product that is:

- Devoid of meaning versus meaningful (*e.g.,* a suffix derived from the name of the license holder)
- unique to each biological product versus unique to each license holder and shared by each biological product manufactured by that license holder.

In your comments, please address how each option would impact the following: Safe use of biological products; pharmacovigilance; and market acceptance and uptake for certain products.

2. What would be the potential benefits and challenges for an interchangeable product [2] to share the same suffix as designated in the proper name of the reference product? Your response should consider that FDA's publicly available electronic resource, the *Purple Book*,[3] will identify biological products determined by FDA to be biosimilar to or interchangeable with a reference product. If an interchangeable product does share the same suffix as the reference product, how would this impact your responses to question 1, including pharmacovigilance?

3. Would there be additional benefits or challenges if the suffix designated in the proper name of a biosimilar product that is subsequently determined to be interchangeable were changed to that of the reference product upon a determination of interchangeability? Would there be benefits or challenges to allowing the manufacturer of the biosimilar product that is subsequently determined to be interchangeable to have the option of retaining its original suffix or adopting the same suffix as the reference product?

4. How could FDA and/or other Federal partners improve active pharmacovigilance systems for purposes of monitoring the safety of biological products? For example, because NDC numbers are not routinely recorded in billing and patient records in many clinical settings in which biological products are dispensed and administered, are there other identifiers besides distinguishable nonproprietary names that are routinely accessible by active pharmacovigilance systems and could enable as good as or better pharmacovigilance? How can FDA and/or other Federal partners help ensure that a distinguishable identifier for each biological product would be captured at the point of dispensing or administration to the patient and be routinely accessible in systems used for pharmacovigilance?

5. What process and reasonable timeframe should FDA use to designate a suffix to include in the nonproprietary name of a previously licensed biological product?

6. What criteria should FDA use to prioritize retrospective application of this naming convention to previously licensed biological products?

7. What are the expected time frames for sponsors of previously licensed biological products to distribute products that conform to this naming convention after approval of a labeling supplement?

8. What strategies could FDA use to enhance stakeholders' understanding of and education about this naming convention?

9. FDA notes that this naming convention (*i.e.,* use of a suffix) has

[1] The BPCI Act was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010.

[2] *Interchangeable product* means a biological product that has been shown to meet the standards described in section 351(k)(4) of the PHS Act and may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product (see section 351(i)(3) of the PHS Act).

[3] The *Purple Book: Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluation* is available on FDA's Web site at *http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm.*

some similarities to the World Health Organization (WHO) proposal, ''Biological Qualifier—An INN Proposal.'' At the time of publication of this draft guidance, WHO was still evaluating the comments received on its proposal. If WHO adopts a Biological Qualifier proposal, how should the biological qualifiers generated by WHO be considered in the determination of FDA-designated proper names for the biological products within the scope of this guidance?

We are continuing to consider the transition provisions of section 7002(e)(2) through (e)(4) of the BPCI Act that apply to biological products submitted or approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act), including how those provisions may impact the nonproprietary naming of products to which those provisions apply. We invite comment from all stakeholders on the application of this naming convention to biological products approved under the FD&C Act.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonproprietary naming of biological products, including biosimilar products and interchangeable products. 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. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance proposes a new collection of information by requesting information from applicants and application holders to propose a suffix composed of four lowercase letters to be included in the ''proper name.'' The ''proper name'' is designated by FDA at the time of licensure for biological products submitted under section 351(a) of the PHS Act and for biosimilar products and interchangeable products submitted under section 351(k) of the PHS Act. The applicant should also include information that the proposed suffix meets the factors described in the draft guidance. For the prospective application of this naming convention, our evaluation will generally occur during the investigational new drug application phase and will also be incorporated into the review of the marketing application.

The draft guidance also refers to a previously approved collection of information found in FDA regulations that is expected to change as a result of the draft guidance and the retrospective application of the naming convention. The collection of information is related to the following: The submission of a biologics license application (BLA) and changes to an approved application, which is covered under part 601 (21 CFR part 601) and approved under OMB control number 0910–0338. As a result of the draft guidance, the estimated number of additional responses for the annual burden for changes to an approved application under § 601.12 would be increased by approximately 25 responses.

The draft guidance also refers to previously approved collections of information found in FDA regulations that are not expected to change as a result of the draft guidance. The collection of information is related to the following: The submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products), which is approved under OMB control number 0910–0719.

FDA estimates the burden of this collection of information for the prospective application of the naming convention as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Information for the Proposed Proper Name for Biological Products Submitted Under Section 351(a) of the PHS Act	20	2	40	6	240
Information for the Proposed Proper Name for Biosimilar Products and Interchangeable Products Submitted Under Section 351(k) of the PHS Act	3	2	6	6	36
Total					276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As indicated in table 1, we estimate that we will receive a total of approximately 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 the Agency's experience with similar information collection requirements.

IV. Electronic Access

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

Dated: August 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21383 Filed 8–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0404]

Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order; Guidance for Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for tobacco retailers entitled ''Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order.'' The guidance represents FDA's current thinking with respect to imposing no-tobacco-sale orders (NTSOs) on retailers who have committed repeated violations of certain restrictions on the sale and distribution of tobacco products. This guidance discusses, among other things, the period of time covered by an NTSO and a retailer's compliance with an NTSO.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen Maschal, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for tobacco retailers entitled ''Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order.'' On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to give FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations that restrict the sale and distribution of tobacco products if FDA determines such regulations would be appropriate for the protection of the public health. Section 303(f)(8) of the FD&C Act (21 U.S.C. 333(f)(8)) authorizes FDA to impose an NTSO against a person found to have committed repeated violations, at a particular retail outlet, of restrictions on the sale and distribution of tobacco products issued under section 906(d) of the FD&C Act, such as FDA's ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (21 CFR part 1140). The term ''no-tobacco-sale order'' refers to an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time under section 303(f)(8) of the FD&C Act. A ''repeated violation'' means ''at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation . . .'' (section 103(q)(1)(A) of the Tobacco Control Act).

FDA conducts inspections of retail outlets to evaluate compliance with the requirements of the FD&C Act and its implementing regulations. This guidance discusses the period of time to be covered by an NTSO where there is evidence of ''repeated violations'' at a particular retail outlet. It also discusses a retailer's compliance with an NTSO. This guidance is meant to supplement FDA's guidances entitled ''Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers'' and ''Civil Money Penalties for Tobacco Retailers and No-Tobacco-Sale Orders: Responses to Frequently Asked Questions.''

In the **Federal Register** of May 13, 2015 (80 FR 27318), FDA announced the availability of the draft guidance of the same title. FDA received comments on the draft guidance and those comments were considered as the guidance was finalized.

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 with respect to the period of time to be covered by NTSOs and retailers' compliance with NTSOs. 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. Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://*