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]

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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://*

www.regulations.gov. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *http://www.regulations.gov.* For this docket, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: August 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21271 Filed 8–27–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

RIN 0906–AB08

340B Drug Pricing Program Omnibus Guidance

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' This notice proposes guidance for covered entities enrolled in the 340B Program and drug manufacturers that are required by section 340B of the PHSA to make their drugs available to covered entities under the 340B Program. When finalized after consideration of public comments solicited by this notice, the guidance is intended to assist 340B covered entities and drug manufacturers in complying with the statute.

DATES: Submit comments on or before October 27, 2015.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB08, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions. The first is the preferred method.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email: 340BGuidelines@hrsa.gov.* Include RIN 0906–AB08 in the subject line of the message.
- *Mail:* Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, Maryland 20857.

All submitted comments will be available to the public in their entirety.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, OPA, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, Maryland 20857, or by telephone at (301) 594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (PHSA) ''Limitation on Prices of Drugs Purchased by Covered Entities,'' codified at 42 U.S.C. 256b. The intent of the 340B Program is to permit covered entities ''to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' H.R. REP. No. 102–384(II), at 12 (1992). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, and only include health care organizations that have certain Federal designations or receive funding from specific Federal programs. These include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics. Section 7101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (''Affordable Care Act'') expanded the types of covered entities eligible to participate in the 340B Program. As of January 1, 2015, there were 11,530 registered covered entities participating in the 340B Program.

Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers. If a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed 340B ceiling prices as defined by statute. HRSA calculates the ceiling prices quarterly using pricing data reported to the Centers for Medicare & Medicaid Services (CMS). Pursuant to section 340B(a)(1) of the PHSA, the 340B ceiling price is calculated by subtracting the Unit Rebate Amount from the Average Manufacturer Price. As of January 1, 2015, there were 644 drug manufacturers participating in the 340B Program.

When an eligible entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Since 1992, HHS has interpreted the statutory requirements of the 340B Program through guidances published in the **Federal Register**, typically after notice and opportunity for comment. HHS is proposing this omnibus guidance to provide increased clarity in the marketplace for all 340B Program stakeholders and strengthen HHS's ability to administer the 340B Program effectively. This notice clarifies many current 340B Program guidances. HHS encourages all stakeholders to provide comments on this proposed guidance.

In September 2010, HHS published two advanced notices of proposed rulemaking in the **Federal Register**,