ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
General Public—Adults	HIV-negative MSM In-Depth Interview Guide—English.	105	1	1	105
General Public—Adults	HIV-negative In-Depth Interview Guide—Spanish.	45	1	1	45
Total					192

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–11512 Filed 5–12–15; 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Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order; Draft Guidance for Tobacco Retailers; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for tobacco retailers entitled ''Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order.'' The draft guidance, when finalized, will represent FDA's current thinking with respect to imposing no-tobacco-sale orders (NTSOs) on retailers who have committed repeated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 This draft guidance discusses, among other things, the period of time covered by an NTSO and a retailer's compliance with an NTSO.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 29, 2015.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm.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self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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. 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, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–877–287–1373, *colleen.maschal@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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 implementing regulations. This draft 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 draft 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.''

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking with respect to the period of time to be covered by NTSOs and retailers' compliance with NTSOs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Requests for 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 draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: May 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11538 Filed 5–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1246]

Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.'' This draft guidance is intended to advise the sponsors and individuals involved in the design and implementation of nonclinical studies on the substance and scope of nonclinical information needed to support first-in-human clinical trials, ongoing clinical development, and eventual approval of enzyme replacement therapy (ERT) products for the treatment of rare, life-threatening conditions.

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 by July 13, 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. 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: Sushanta Chakder, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5108, Silver Spring, MD 20993–0002, 301–796–0861.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment.''

This draft guidance provides sponsors and individuals involved in the design and implementation of nonclinical studies with recommendations on the nonclinical information needed to support initiation of clinical trials, ongoing clinical development, and eventual licensure or approval for investigational ERT products. The recommendations in this guidance are applicable to ERT products indicated for lysosomal storage diseases or other diseases related to inborn errors of metabolism.

Because of the wide array of clinical indications, natural history of disease, and product types, no single nonclinical program can be designed to address all ERT products, and a case-by-case approach to both toxicological evaluation and clinical development is warranted to optimize and expedite drug development. Common nonclinical issues, such as the number of animal species needed for safety assessment, selection of animal models and duration of the toxicology studies needed to support first-in-human trials, and nonclinical study requirements for ultimate licensure or market approval of the ERT product, are addressed in this guidance.

This guidance is intended as an adjunct to the ICH guidances for industry entitled ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals,'' ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals—Questions and Answers,'' and ''S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals.''

This draft guidance is being issued consistent with FDA's good guidance