facilities. This alternative interim registration method relies on email and is only intended for use in the near term while outsourcing facilities unfamiliar with registration familiarize themselves with the SPL format. FDA encourages outsourcing facilities that choose to use this alternative interim method to begin using the SPL format no later than September 30, 2014. In addition, outsourcing facilities may request a waiver from the electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

Because human drug compounders are not currently required to register and report as outsourcing facilities, it is difficult to anticipate the number of outsourcing facilities that will participate in the process.

Estimated reporting burden until September 30, 2014. We estimate that approximately 15 outsourcing facilities (''number of respondents'' and ''total responses'' in table 1 row 1) will submit registration information to FDA using email as specified in the draft guidance, and that preparing and submitting this information will take approximately 15 minutes (''average burden per response'' in table 1 row 1). We also estimate that approximately 5 outsourcing facilities (''number of respondents'' and ''total responses'' in table 1, row 2) will submit to FDA registration information using the SPL format as specified in the draft guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant (''average burden per response'' in table 1, row 2). We expect to receive no more than one waiver request from the electronic submission process during this time period (''number of respondents'' and ''total responses'' in table 1, row 3), and that each request should take approximately 1 hour to prepare and submit to us (''average burden per response'' in table 1, row 3).

Estimated annual reporting burden after September 30, 2014. We estimate that approximately 20 outsourcing facilities (''number of respondents'' and ''total annual responses'' in table 2, row 1) will annually submit to FDA registration information using the SPL format as specified in the draft guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant (''average burden per response'' in table 2, row 1). We expect to receive no more than one waiver request from the electronic submission process annually (''number of respondents'' and ''total annual responses'' in table 2, row 2), and that each request should take approximately 1 hour to prepare and submit to us (''average burden per response'' in table 2, row 2).

TABLE 1—ESTIMATED REPORTING BURDEN UNTIL SEPTEMBER 30, 2014 [1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Alternative Interim Registration Method Using Email	15	1	15	0.25	3.75
Electronic Submission of Registration Information Using SPL Format	5	1	5	4.5	22.50
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					27.25

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN AFTER SEPTEMBER 30, 2014 [1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using SPL Format	20	1	20	4.5	90
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					91

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

III. 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.*

IV. Electronic Access

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

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28962 Filed 12–2–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1083]

Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.'' This guidance provides information in response to questions that FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products in retail outlets.

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

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

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: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, email: *gerie.voss@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.'' In this guidance, FDA addresses questions regarding the issuance of civil money penalties for violations of tobacco product regulations. In the **Federal Register** of February 8, 2013 (78 FR 9396), FDA announced the availability of the draft guidance of the same title. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

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 Agency's current thinking on this topic. 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 statute and regulations.

III. 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*.

IV. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28961 Filed 12–3–13; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013-D–1444]

Draft Guidance; Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Withdrawal of Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act''. The draft guidance announces the Agency's intention with regard to enforcement of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to regulate entities that compound drugs, now that the FD&C Act has been amended by the Drug Quality and Security Act. When final, the guidance will reflect the Agency's current thinking on the issues addressed by the guidance.

The Agency is also announcing the withdrawal of a guidance entitled, ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act,'' which was issued in November 1998, and the withdrawal of CPG Section 460.200 of the Compliance Program Guidance (CPG) Manual entitled, ''Pharmacy Compounding,'' which was issued in May 2002. These guidances are being withdrawn because they are no longer consistent with the Agency's current thinking on the issues they address.

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 the draft guidance by February 3, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy, Office of Enforcement, Food and Drug Administration, rm. 4025, 12420 Parklawn Dr., Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Announcement of Draft Guidance

FDA is announcing the availability of a draft guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance provides information to compounders of human drug products and to FDA staff on the Agency's application of section 503A of the FD&C Act (21 U.S.C. 353a) and current enforcement policies relating to the compounding of human drug products.

Section 503A of the FD&C Act describes the conditions that must be