4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0030]

Extension of the Period Before the Food and Drug Administration Intends to Begin Enforcing the Statutory 5 Percent Limit on Out of State Distribution of Compounded Human Drug Products

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; extension of the period before FDA intends to begin enforcing the statutory 5 percent limit on out of state distribution of compounded human drug products.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the period for States to decide whether to sign the final standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (final standard MOU) before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU. FDA is extending the period, which was scheduled to end on October 27, 2021, to October 27, 2022. States may sign the final standard MOU at any time, including after the period is scheduled to end on October 27, 2022.

DATES: FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993-0002, 240-402-4078.

SUPPLEMENTARY INFORMATION: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician in a State licensed pharmacy or a Federal facility, to be exempt from the following sections of the FD&C Act: (1) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (statutory 5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

In the *Federal Register* of October 27, 2020 (85 FR 68074), FDA announced the availability of the final standard MOU describing the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the final standard MOU in investigating and responding to complaints related to drug products compounded in such State

and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

In the October 27, 2020, *Federal Register* notice, FDA stated that it was providing a 365-day period for States to decide whether to sign the final standard MOU before FDA intended to begin enforcing the statutory 5 percent limit in States that do not sign the final standard MOU. Based on comments from stakeholders, it was FDA's understanding that this timeframe corresponds to a full legislative cycle for most States and would, therefore, afford sufficient time for States to modify their laws and regulations, if necessary in order to enter into the final standard MOU.

Following publication of October 27, 2020, *Federal Register* notice, FDA received requests to extend the period before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign. The requesters asserted that the time period of 365 days was insufficient to allow State governments to thoroughly evaluate the final standard MOU and modify their laws and regulations, if necessary in order to sign, because many State governments were focused on addressing concerns raised by the Coronavirus Disease 2019 (COVID-19) pandemic.

FDA has considered the requests and other relevant factors and is extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign the final standard MOU until October 27, 2022. FDA believes that an additional 1 year will allow sufficient time for States to consider the final standard MOU and modify their laws and regulations, if necessary. FDA's understanding is that emergency pandemic response activities have now begun to ease, permitting States more time to take up other issues. Accordingly, we believe a 1-year extension addresses the need that some States have expressed for additional time, without adding significant delay to FDA's implementation of the important public health protections afforded by section 503A(b)(3)(B) of the FD&C Act.

States may sign the final standard MOU at any time, including after the period is scheduled to end on October 27, 2022.

Dated: August 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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