

compliance with the final rule, entitled “Aluminum Import Monitoring and Analysis System,” by staying the regulations from March 29, 2021, until June 28, 2021. Commerce will release the public Aluminum Import Monitoring and Analysis (AIM) monitor on the AIM system website on March 29, 2021.

**DATES:** As of March 29, 2021, compliance with the final rule published December 23, 2020 at 85 FR 83804 and amended January 27, 2021 at 86 FR 7237 is delayed and 19 CFR part 361 is stayed until June 28, 2021. The public AIM monitor will be released on the AIM system website on March 29, 2021.

**ADDRESSES:** The AIM system website is <https://www.trade.gov/aluminum>. Commerce will release the public AIM monitor using publicly available data through this website on March 29, 2021. More information can be found in the *Final Rule* and at <https://www.trade.gov/updates-aluminum-import-licensing>. Commerce is offering virtual demonstrations of the public AIM monitor, which are available to the general public. Although the demonstrations will be completely virtual, Commerce will have a limited number of spots available for participation in the demonstrations. For specific dates and times of the demonstrations, and to participate in the demonstrations, please visit <https://www.trade.gov/updates-aluminum-import-licensing>.

**FOR FURTHER INFORMATION CONTACT:** Julie Al-Saadawi at (202) 482–1930 or Jessica Link at (202) 482–1411.

**SUPPLEMENTARY INFORMATION:** On December 23, 2020, Commerce published “Aluminum Import Monitoring and Analysis System,” (*Final Rule*) establishing the AIM system in part 361 that would be comprised of an aluminum import licensing program and a public AIM monitor, available through the AIM system website.<sup>1</sup> On January 4, 2021, Commerce launched the AIM system website (<https://www.trade.gov/aluminum>). The original effective date for part 361 was January 25, 2021, meaning that licenses would be required for all covered aluminum imports on or after this date.

On January 27, 2021, Commerce published a notification delaying the effective date of the AIM system until March 29, 2021, and opening a 30-day comment period to solicit public

comment, on the January 27 notification, that closed on February 26, 2021, on all aspects of the *Final Rule* and the AIM system.<sup>2</sup>

Upon receipt and consideration of the public comment,<sup>3</sup> Commerce has determined that it is appropriate to delay compliance with most aspects of part 361 and the AIM system by an additional ninety days, by staying part 361. This delay will allow Commerce time to finalize the license application system and to provide both the public and U.S. Customs and Border Protection (CBP) with sufficient advance notice of the new compliance date. In addition, the delay will allow Commerce to consider and respond, as appropriate, to the comments; Commerce intends to issue another notification addressing these comments prior to June 28, 2021.

Therefore, unless otherwise announced, compliance for the majority of part 361 and the AIM system will be effective on June 28, 2021, meaning that licenses will be required for all covered aluminum imports on or after this date. Additionally, the remaining portions of the regulations concerning the removal of the option to state “unknown” for certain fields on the aluminum license form will be effective on December 24, 2021, as stated in the relevant sections of part 361, unless otherwise announced. For further background and information, see the *Final Rule*. Further guidance on licenses already issued and the issuance of new licenses in the intervening period before June 28, 2021 will be provided on the AIM system website.

Although Commerce is delaying compliance with the majority of part 361 and the AIM system as described above, Commerce is moving forward with one aspect of the AIM system on March 29, 2021. Specifically, Commerce will release the public AIM monitor on the AIM system website on March 29, 2021. When released, the public AIM monitor will provide information on U.S. imports of aluminum from all countries by broad product categories in both value and volume measures. The public AIM monitor will initially only include publicly available import data, as the license information will not be available. Once the license collection begins, and Commerce has had sufficient time to review the license data, the public AIM monitor will report certain aggregate information on imports

<sup>2</sup> *Aluminum Import Monitoring and Analysis System: Delay of Effective Date*, 86 FR 7237 (January 27, 2021).

<sup>3</sup> These comments can be found by searching for the *Final Rule* (Docket No. ITA–2021–0001) on the Federal eRulemaking portal at <http://www.regulations.gov>.

of aluminum product categories using both publicly available import data and data obtained from the aluminum licenses.

Releasing the public AIM monitor, while delaying compliance with the license application system, is consistent with the historical release of the early Steel Import Monitor and Analysis (SIMA) monitor. When SIMA was first launched in early 2003, an early version of the SIMA monitor was released with only public data.<sup>4</sup> This provided the public some details about what the monitor may look like and created public interest in SIMA before the implementation of the license application system. Commerce finds it appropriate to adopt a similar approach in this instance for the AIM system.

This is a significant rulemaking under Executive Order 12866 but it is not economically significant.

#### List of subjects in 19 CFR Part 361

Administrative practice and procedure, Business and industry, Imports, Reporting and recordkeeping requirements, Aluminum.

For the reasons stated in the preamble and under the authority of 13 U.S.C. 301(a) and 302, the Department of Commerce stays 19 CFR part 361 until June 28, 2021.

Dated: March 29, 2021.

**Christian Marsh,**

*Acting Assistant Secretary for Enforcement and Compliance.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1

[Docket No. FDA–2016–N–1487]

#### Electronic Import Entries; Technical Amendments

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

**ACTION:** Final rule; technical amendments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is amending its electronic import entries regulation to correct the statutory citation in the sections of that regulation requiring submission of the

<sup>4</sup> *Steel Import Licensing and Surge Monitoring*, 67 FR 79845 (Dec. 31, 2002).

<sup>1</sup> *Aluminum Import Monitoring and Analysis System*, 85 FR at 83804 (December 23, 2020) (*Final Rule*).

Drug Registration Number for human drugs and for animal drugs. The present revisions are necessary to correct editorial errors and to ensure that the codified cites the correct section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The electronic import entries regulation provides that the Drug Registration Number, which must be submitted at the time of entry in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by the U.S. Customs and Border Protection Agency (CBP), is the unique facility identifier specified in the FD&C Act. This rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

**DATES:** This rule is effective April 1, 2021.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Ann Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20903-0002, 301-796-3324, [Ann.Metayer@fda.hhs.gov](mailto:Ann.Metayer@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of November 29, 2016 (81 FR 85854), FDA published a final rule that established requirements for the electronic filing of entries for FDA-regulated products in the ACE or any other EDI system authorized by the CBP. The rule requires the submission of the Drug Registration Number for human and animal drugs in ACE at the time of entry. The Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human or animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the FD&C Act (21 U.S.C. 360).

**II. Description of the Technical Amendments**

We are amending the electronic import entries regulation to revise the statutory citation in the sections of that rule requiring submission of the Drug Registration Number for human drugs regulated by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and for animal drugs regulated by FDA's Center for Veterinary Medicine. The sections of the regulation specified in this rule, specifically 21 CFR 1.74(a)(1), 1.75(a), and 1.78(d), have been revised to change the reference from section 510(b) of the FD&C Act to section 510 of the FD&C Act, which is the correct statutory citation. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

**III. Notice and Public Comment**

Publication of this document constitutes final action of these changes under the Administrative Procedures Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts "rules of agency organization, procedure, or practice" from proposed rulemaking (*i.e.*, notice and comment rulemaking) (5 U.S.C. 553(b)(3)(A)). Rules are also exempt when an Agency finds "good cause" that notice and comment rulemaking procedures would be "impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(3)(B).)

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make technical or nonsubstantive changes that pertain solely to ensuring that the regulations accurately cite the FD&C Act. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as "provided by the agency for good cause and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

**List of Subjects in 21 CFR Part 1**

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 1 is amended as follows:

**PART 1—GENERAL ENFORCEMENT REGULATIONS**

■ 1. The authority citation for part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

■ 2. Revise the third sentence of § 1.74(a)(1) to read as follows:

**§ 1.74 Human drugs.**

\* \* \* \* \*  
(a) \* \* \*  
(1) \* \* \* The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. \* \* \*

■ 3. Revise the third sentence of § 1.75(a) to read as follows:

**§ 1.75 Animal drugs.**

\* \* \* \* \*  
(a) \* \* \* The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. \* \* \*

■ 4. Revise the last sentence of § 1.78(d) to read as follows.

**§ 1.78 Biological products, HCT/Ps, and related drugs and medical devices.**

\* \* \* \* \*  
(d) \* \* \* The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. \* \* \*

Dated: March 25, 2021.  
**Xavier Becerra,**  
*Secretary, Department of Health and Human Services.*  
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