4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA-2015-N-2103]

Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to remove two regulations that prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972. FDA is taking this action because the two regulations are obsolete and no longer necessary in light of other statutory and regulatory authorities established since 1972, which allow FDA to evaluate and monitor the safety and effectiveness of all biological products. In addition, other statutory and regulatory authorities authorize FDA to revoke a license for products because they are not safe and effective, or are misbranded. FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation.

DATES: Submit either written or electronic comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-2103 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Proposed Rule

FDA proposes to remove two regulations that prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972, because the two regulations are obsolete and no longer necessary in light of other statutory and regulatory authorities established since 1972. These other statutory and regulatory authorities allow FDA to evaluate and monitor the safety and effectiveness of all biological products and authorize FDA to revoke a license for products because they are not safe and effective, or are misbranded.

Statement of Legal Authority

FDA is taking this action under the biological products provisions of the Public Health Service Act (the PHS Act), and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

Summary of the Major Provisions of the Proposed Rule

The proposed rule removes §§ 601.25 and 601.26 (21 CFR 601.25 and 601.26), which prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972.

Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

I. Background

In the Federal Register of March 15, 1972 (37 FR 5404), the Director of the National Institutes of Health (NIH) announced that the Division of Biologics Standards, NIH would review the effectiveness of all licensed biologicals. In the Federal Register of June 29, 1972

(37 FR 12865), FDA announced the transfer of regulatory authority of biological products from the Division of Biologics Standards, NIH to FDA. After obtaining regulatory authority of biological products, the Commissioner of FDA proposed procedures for reviewing the safety, effectiveness, and labeling of all biological products licensed at the time of the transfer, including biological products licensed before July 1, 1972 (37 FR 16679, August 18, 1972). The procedures for review of biological products licensed before July 1, 1972, were codified in 21 CFR 273.245 (38 FR 4319 at 4321, February 13, 1973) and later redesignated to § 601.25 (38 FR 32048, November 20, 1973). The procedures for review of biological products licensed before July 1, 1972, were supplemented by procedures codified in § 601.26 (47 FR 44062, October 5, 1982).

II. Current Methods for Ensuring the Safety and Effectiveness of Biological Products.

Since providing the procedures under §§ 601.25 and 601.26, FDA established many new regulations to assess and ensure the safety and efficacy of biological products. FDA established the Current Good Manufacturing Practice (cGMP) regulations, which contains the minimum current good manufacturing practice for preparation of drug products, including biological products. The cGMP regulations help FDA ensure that such products meet the requirements for product safety, effectiveness, and labeling. FDA also ensures the safety and effectiveness of biological products through application of other regulations, such as the reporting of biological product deviations by licensed manufacturers (see 21 CFR 600.14), postmarketing reporting of adverse experiences (21 CFR 600.80), and labeling regulations (for example, 21 CFR part 201). Biological products that do not meet the requirements under these regulations are subject to license revocation under § 601.5, which allows FDA to revoke any biologics license for a

product that fails to meet applicable standards and comply with regulations designed to ensure the safety, purity, and potency of the licensed product, and that the product is not misbranded.

In addition, FDA continues to ensure the safety and effectiveness of licensed biological products through the development and application of additional standards and mechanisms. These mechanisms assist FDA in evaluating and monitoring the safety and effectiveness of biological products.

III. Description of the Proposed Rule

The proposed rule removes §§ 601.25 and 601.26 of the regulations, which prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972. FDA is taking this action because these regulations are obsolete and no longer necessary in light of other statutory and regulatory authorities established since 1972, which allows FDA to evaluate and monitor the safety and effectiveness of all biological products.

IV. Legal Authority

FDA is issuing this regulation under the biological products provisions of the PHS Act (42 U.S.C. 262 and 264) and the drugs and general administrative provisions of the FD&C Act (sections 201, 301, 501, 502, 503, 505, 510, 701, and 704) (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, and 374). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent; and to prevent the introduction, transmission, and spread of communicable disease.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule proposes to remove regulations that are obsolete and no longer necessary in light of other current statutory and regulatory authorities, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment.

Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

IX. 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.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the FD&C Act, the PHS Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 601 be amended as follows:

PART 601--LICENSING

1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451-1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105-115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.25 [Removed]

2. Remove § 601.25.

§ 601.26 [Removed]

3. Remove § 601.26.

Dated: June 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-16367 Filed: 7/1/2015 08:45 am; Publication Date: 7/2/2015]