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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is removing 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. 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.

B. Summary of the Major Provisions of the Final Rule

The final 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.

C. 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).

D. Costs and Benefits

Because this final 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.

II. Background

A. History of the Rulemaking

In the Federal Register of July 2, 2015 (80 FR 38145), FDA proposed to remove regulations that prescribe procedures for FDA’s review and classification of biological products licensed before July 1, 1972. As discussed in the preamble to the proposed rule, these regulations were originally issued after the Director of the National Institutes of Health (NIH) announced in the Federal Register on March 15, 1972, that the Division of Biologics Standards, NIH, would review the effectiveness of all licensed biologicals (37 FR 5404). In the Federal Register of June 29, 1972 (37 FR 12865), FDA announced the transfer of regulatory authority over biological products from the Division of Biologics Standards, NIH, to FDA. After obtaining regulatory authority over 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 on 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).

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

Since establishing the procedures under §§ 601.25 and 601.26, FDA developed new regulations to assess and ensure the safety and efficacy of biological products. FDA issued the Current Good Manufacturing Practice (cGMP) regulations, which contain the minimum cGMP 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 helps ensure 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 21 CFR 601.5, which allows FDA to revoke any biologics license for a product that fails to meet applicable standards and fails to comply with...
The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule removes regulations that are obsolete and no longer necessary in light of other current statutory and regulatory authorities, FDA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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. This final rule would not result in any 1-year expenditure that would meet or exceed this amount.

V. Analysis of Environmental Impact

We have 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.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does 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 has concluded that the 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.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

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


§ 601.25 [Removed]

2. Remove § 601.25.

§ 601.26 [Removed]


Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868 and 870

[Docket No. FDA–2012–N–1174]

Anesthesiology Devices; Reclassification of Membrane Lung for Long-Term Pulmonary Support; Redesignation as Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to redesignate membrane lung devices for long-term pulmonary support, a preamendments class III device, as extracorporeal circuit and accessories for long-term respiratory/ cardiopulmonary failure, and to reclassify the device to class II (special controls) in patients with acute respiratory failure or acute cardiopulmonary failure where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. A membrane lung device for long-term pulmonary support (>6 hours) refers to the oxygenator in an extracorporeal circuit used during long-term procedures, commonly referred to as

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