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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 601, 620, 630, 640, 650, 660, and 680

[Docket No. 95N-310B]

Revocation of Certain Regulations; Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to remove certain biologics regulations that are obsolete or no longer necessary to achieve public health goals. These regulations were identified for removal as the result of a **page-by-page** review of the agency's regulations. This regulatory review is in response to the Administration's ``Reinventing Government'' initiative which seeks to streamline government to ease the burden on regulated industry and consumers.

EFFECTIVE DATE: August 12, 1996.

FOR FURTHER INFORMATION CONTACT:

Regarding general information on FDA's ``reinventing initiative'':
Lisa M. Helmanis, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

Regarding biologics regulations: Annette A. Ragosta, Center for

Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the Administration's ``Reinventing Government'' initiative. In his March 4 directive, the President ordered all Federal agencies to conduct a **page-by-page** review of their regulations and to ``eliminate or revise those that are outdated or otherwise in need of reform.'' In the Federal Register of October 13, 1995 (60 FR 53480), FDA issued a notice of proposed rulemaking in which FDA proposed to remove a number of outdated or unnecessary regulations in parts 100 through 801 (21 CFR parts 100 through 801). The regulations proposed for removal apply to a variety of products regulated by FDA, including foods, drugs, veterinary drugs, biological products, and devices. Interested persons were requested when submitting comments to identify the FDA Center responsible for the regulation of the product to which the comments applied. In order to expedite matters, the final rules resulting from the line-by-line review are being issued separately by FDA Centers. FDA is issuing this final rule, which eliminates

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certain regulations affecting biological products in parts 600 through 680.

II. Comments

FDA received two comments on the proposed rule that related to the biologics regulations. One comment was general in nature and urged Congress to include FDA reform as a top priority in 1996.

Congress is currently considering legislation that would affect FDA programs and procedures. FDA has testified at congressional hearings on

the pending bills. The agency does not believe it would be appropriate to comment on the ongoing legislative initiatives in this rulemaking.

The agency agrees with the comment that regulatory programs and regulations that implement them should be reviewed and revised or reformed where appropriate. FDA is currently reviewing other biologics regulations, the potential removal or revision of which involves issues

of greater regulatory complexity and, based on this review, will remove

or significantly revise these regulations at a later date. In addition,

a number of changes to the regulations and policies affecting biological products are already underway. (See for example, ``Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized

Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products'' (60 FR 63048, December 8, 1995); ``Well-Characterized Biotechnology Products; Elimination of Establishment License Application'' (61 FR 2733, January 29, 1996); ``Changes to an Approved Application'' (61 FR 2739); ``Draft Guidance; Changes to an Approved Application for Well-Characterized Therapeutic Recombinant

DNA-Derived and Monoclonal Antibody Biotechnology Products; Availability'' (61 FR 2748); ``Changes to an Approved Application; Draft Guidance; Availability'' (61 FR 2749).) This final rule,

``Revocation of Certain Regulations; Biological Products,'' is one part

of the agency's efforts to create a more efficient and responsive regulatory system.

The other comment received was supportive of the proposed rule and stated that it was a good first step in reducing regulatory burden.

The comment suggested the incorporation of the United States Pharmacopeia (USP) monograph system based on the Center for Drug Evaluation and Research model into the Center for Biologics Evaluation and Research's regulatory reform process.

The agency does not agree with this suggestion because biologics, for which FDA is removing additional standards from the regulations, are complex and diverse entities. Monographs for many types of biological products could become quickly outdated in the rapidly evolving field of biotechnology, as did the Additional Standards in parts 620, 630, 640, 650, 660, and 680, which this final rule is removing. Use of monographs would allow for less flexibility in the

development of product specifications for complex biologicals.

III. Effective Date

As provided under 5 U.S.C. 553(d) and Sec. 10.40(c) (21 CFR 10.40(c)), the effective date of a final rule may not be less than 30 days after the date of publication, except for, among other things, a regulation that grants an exemption or relieves a restriction' (Sec. 10.40(c)(4)(i)). The final rule is effective August 12, 1996.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed removals have no compliance costs and do not result in any new requirements, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an

environmental assessment nor an environmental impact statement is required.

st of Subjects

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 620

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 630

Biologics, Labeling.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

CFR Part 650

Biologics.

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 601, 620, 630, 640, 650, 660, and 680 are amended as follows:

PART 601--LICENSING

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

Authority: Secs. 201, 501, 502, 503, 505, 510, 513-516, 518-520, 701, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 374, 39e, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461).

Sec. 601.30 [Removed]

2. Section 601.30 Licenses required; products for controlled investigation only is removed.

Sec. 601.31 [Removed]

3. Section 601.31 Procedure is removed.

Sec. 601.32 [Removed]

4. Section 601.32 Form of license is removed.

PART 620--ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS--

Part 620 [Removed]

5. Part 620 is removed.

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PART 630--ADDITIONAL STANDARDS FOR VIRAL VACCINES

Part 630 [Removed]

6. Part 630 is removed.

PART 640--ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

7. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

Subpart K [Removed and Reserved]

8. Subpart K, consisting of Secs. 640.110 through 640.114, is removed and reserved.

PART 650--ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

Part 650 [Removed]

9. Part 650 is removed.

PART 660--ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

10. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

Subpart K [Removed]

11. Subpart K, consisting of Secs. 660.100 through 660.105, is removed.

PART 680--ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

12. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

13. The heading for Subpart A--Allergenic Products is removed.

Subpart B [Removed]

14. Subpart B, consisting of Secs. 680.10 through 680.16, is removed.

Subpart C [Removed]

15. Subpart C, consisting of Secs. 680.20 through 680.26, is removed.

Dated: July 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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