

FDC date	State	City	Airport	FDC No.	SIAP
06/27/96	ID	McCall	McCall	FDC 6/4222	NDB or GPS-A, ORIG...
07/02/96	UT	Logan	Logan-Cache	FDC 6/4430	VOR or GPS-A AMDT 6... THIS CORRECTS NOTAM IN 96-16
07/11/96	MN	Brainerd	Brainerd-Crow Wing County Regional	FDC 6/4731	VOR or GPS RWY 30 AMDT 13...
07/12/96	NE	Lincoln	Lincoln Muni	FDC 6/4755	ILS RWY 35L, AMDT 11A...
07/12/96	NEdodo	FDC 6/4756	ILS RWY 17R, AMDT 6A...
07/16/96	IA	Dubuque	Dubuque Regional	FDC 6/4890	VOR RWY 31, AMDT 11...
07/16/96	IAdodo	FDC 6/4894	NDB or GPS RWY 31, AMDT 8...
07/16/96	IAdodo	FDC 6/4895	VOR OR GPS RWY 13, AMDT 8A...
07/16/96	IAdodo	FDC 6/4896	VOR or GPS RWY 36, AMDT 5A...
07/16/96	IAdodo	FDC 6/4897	ILS RWY 31, AMDT 10A...
07/16/96	IAdodo	FDC 6/4898	LOC/DME BC RWY 13, AMDT 4...
07/17/96	NY	New York	John F. Kennedy Intl	FDC 6/4930	ILS RWY 4R AMDT 28B...
07/17/96	NYdodo	FDC 6/4931	ILS RWY 13L AMDT 14A...
07/18/96	MS	Pascagoula	Trent Lott Intl	FDC 6/4967	ILS RWY 17, ORIG...
07/18/96	NY	New York	John F. Kennedy Intl	FDC 6/4979	VOR/DME or TACAN or GPS RWY 22L AMDT 4...
07/18/96	NYdodo	FDC 6/4980	VOR or GPS RWY 4L/R AMDT 15...
07/18/96	NYdodo	FDC 6/4983	ILS RWY 22L AMDT 22...
07/18/96	NYdodo	FDC 6/4984	ILS RWY 31L AMDT 9...
07/18/96	NYdodo	FDC 6/4985	ILS RWY 31R AMDT 13...
07/19/96	GA	Columbus	Columbus Metropolitan	FDC 6/5010	ILS RWY 5, AMDT 24...
07/22/96	IL	Salem	Salem-Leckrone	FDC 6/5089	NDB or GPS RWY 18, AMDT 8...
07/22/96	NC	Raleigh-Durham	Raleigh-Durham Intl	FDC 6/5092	RADAR-1, AMDT 7...
07/23/96	IA	Charles City	Charles City Muni	FDC 6/5142	NDB-A, ORIG...
07/23/96	IAdodo	FDC 6/5143	LOC RWY 12, ORIG-C...
07/23/96	IAdodo	FDC 6/5144	NDB or GPS RWY 12, ORIG-C...
07/23/96	IA	Fort Madison	Fort Madison Muni	FDC 6/5139	VOR/DME RNAV or GPS RWY 34, AMDT 4...
07/23/96	IAdodo	FDC 6/5140	VOR/DME RNAV or GPS RWY 16, AMDT 4...
07/23/96	IAdodo	FDC 6/5141	VOR/DME or GPS-A, AMDT 6...

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BILLING CODE 4910-13-M

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

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 the 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 Pharmacopoeia (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 § 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" (§ 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 is 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.

List 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.

21 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, 379e, 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).

§ 601.30 [Removed]

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

§ 601.31 [Removed]

3. Section 601.31 *Procedure* is removed.

§ 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.

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 §§ 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 §§ 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 §§ 680.10 through 680.16, is removed.

Subpart C [Removed]

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

Dated: July 19, 1996.
William K. Hubbard,
*Associate Commissioner for Policy
Coordination.*
[FR Doc. 96-19604 Filed 7-31-96; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 735****Grants for Program Development and Administration and Enforcement****CFR Correction**

In Title 30 of the Code of Federal Regulations, parts 700 to End, revised as of July 1, 1995, on page 144, § 735.23 was inadvertently omitted. The omitted text should read as follows:

§ 735.23 Administrative procedures.

The agency shall follow administrative procedures governing accounting, payment, property and related requirements contained in Office of Management and Budget Circular No. A-102.

BILLING CODE 1505-01-D

30 CFR Part 937**Oregon****CFR Correction**

In Title 30 of the Code of Federal Regulations, parts 700 to End, revised as of July 1, 1995, on page 639, § 937.772 was inadvertently omitted. The omitted text should read as follows:

§ 937.772 Requirements for coal exploration.

(a) Part 772 of this Chapter, "Requirements for coal exploration," shall apply to any person who conducts or seeks to conduct coal exploration operations.

(b) The Office shall make every effort to act on an exploration application within 60 days of receipt or such longer time as may be reasonable under the circumstances. If additional time is needed, OSMRE shall notify the applicant that the application is being reviewed, but more time is necessary to complete such review, setting forth the reasons and the additional time that is needed.

(c) Where coal exploration is to occur on State lands or the minerals to be explored are owned by the State, a mineral lease issued by the Oregon Division of Lands authorizing the coal

exploration is required to be filed with the permit application.

[52 FR 13812, Apr. 24, 1987]

BILLING CODE 1505-01-D

FEDERAL COMMUNICATIONS COMMISSION**47 CFR Part 1**

[MD Docket No. 96-84; DA 96-1156]

Assessment and Collection of Regulatory Fees for Fiscal Year 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission revised its Schedule of Regulatory Fees on July 1, 1996, in order to recover the amount of regulatory fees that Congress has required it to collect for fiscal year 1996. See *Report and Order in the Matter of Assessment and Collection of Regulatory Fees for Fiscal Year 1996*, Md Docket 96-84, FCC-295 (released July 5, 1996). The attached *Order* establishes the dates when these regulatory fees must be paid.

EFFECTIVE DATE: August 1, 1996.

DATES: September 30, 1996 for annual fees for Geosynchronous Space Station Licensees, Intelsat and Inmarsat Signatories, and Low Earth Orbit Satellite System Licensees. September 12, 1996, through September 20, 1996, for all other annual fee payors. Beginning on September 12, 1996, for applicants who pay fees in advance in combination with their application fee for new, renewal and reinstatement authorizations in the private wireless services.

FOR FURTHER INFORMATION CONTACT: Peter W. Herrick, Office of Managing Director at (202) 418-0443, or Terry D. Johnson, Office of Managing Director at (202) 418-0445.

SUPPLEMENTARY INFORMATION:

Adopted: July 22, 1996
Released: July 24, 1996

1. The Managing Director has determined the dates for collection of the fees adopted in the fiscal year 1996 regulatory fee proceeding. See *Assessment and Collection of Regulatory Fees for Fiscal Year 1996*, FCC-295 (released July 5, 1996), 61 FR 36629 (July 12, 1996). We are establishing collection dates as indicated below.

2. Annual regulatory fees for Geosynchronous Space Station licensees, Intelsat and Inmarsat Signatories, and Low Earth Orbit