times established by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM CO E5 Montrose, CO [Revised]

Montrose Regional Airport, CO
(Lat. 38°30′32″ N, long. 107°53′38″ W)
Montrose VOR/DME
(Lat. 38°30′23″ N, long 107°53′58″ W)

That airspace extending upward from 700 feet above the surface within 4.3 miles northeast and 8.3 miles southwest of the Montrose VOR/DME 313° and 133° radials extending from 6.1 miles southeast to 21.4 miles northwest of the VOR/DME, and within 4 miles each side of the Montrose VOR/DME 360° radial extending to 9.5 miles north of the VOR/DME; and that airspace extending upward from 1,200 feet above the surface within an area bounded by a point beginning at lat. 38°40′00″ N, long. 108°46′00″ W; to lat. 38°25′00″ N, long. 108°42′30″ W; to lat. 37°58′00″ N, long. 108°10′00″ W; to lat. 38°09′00″ N, long. 107°35′00″ W; to lat. 38°43′00″ N, long. 107°39′30″ W; to lat. 38°51′30″ N, long. 107°41′00″ W; to lat. 38°50′00″ N, long. 107°53′00″ W; to lat. 38°53′00″ N, long. 108°03′30″ W; thence to the point of beginning.

* * * * *

Issued in Seattle, Washington, on January 13, 1997.

Glenn A. Adams III,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 97–2093 Filed 1–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 601, and 606

[Docket No. 96N–0395]

Revision of the Requirements for a Responsible Head for Biological Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by deleting the requirements for a biologics establishment to name a ''responsible head'' or ''designated qualified person'' to represent the establishment in its dealings with FDA. Because many manufacturers of biological products are firms that have more than one manufacturing location and complex corporate structures, it may no longer be practical for one individual to represent a manufacturer in all matters. The proposed rule would provide manufacturers with more flexibility in assigning control and oversight responsibility within a company. This proposed rule is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and it is intended to reduce the burden of unnecessary regulations on industry without diminishing public health protection.

DATES: Comments must be submitted on or before April 29, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Corporations should submit two copies of any comments and individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, 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

Under § 600.10(a) (21 CFR 600.10(a)), a manufacturer of biological products is required to name a ''responsible head'' who is to exercise control of the manufacturing establishment in all matters relating to compliance with regulations in parts 600 through 680 (21 CFR parts 600 through 680) and who is to represent the manufacturer in all pertinent matters with the Center for Biologics Evaluation and Research (CBER). This individual must also have an understanding of the scientific principles and techniques related to the manufacture of biological products. When FDA announced in the Federal Register of June 3, 1994 (59 FR 28821 and 28822), the review by CBER of certain biologics regulations to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary, § 600.10(a) was included. FDA also held a public meeting on January 26, 1995, to discuss the retrospective review effort and to provide a forum for the public to voice its comments on the retrospective review.

Many of the comments submitted requested revision or elimination of the requirements for a ''responsible head'' in § 600.10(a). The majority of the comments supported deletion of the regulation. The comments stated that the requirement for a responsible head to be an expert in multiple functions and to be responsible for a number of facility locations is incompatible with current industry practice. The comments added that the list of activities in § 600.10(a) is extremely broad and this regulation could be interpreted to require the responsible head to have an intimate understanding of a wide variety of extremely complex activities. All of these activities require specific expertise, and it may not be practical to expect one person to be an expert in all of those areas. Some comments addressed the requirement that the responsible head be responsible for training and have the authority to enforce discipline, stating that direct line supervision and management personnel are much better qualified and in a better position to ''enforce or direct the enforcement of discipline and performance of assigned functions by employees engaged in the manufacture of products.'' Many comments requested the designation of an alternate responsible head, especially in the situation of multiple locations.

As part of the President's ''Reinventing Government'' initiative, a report entitled ''Reinventing the Regulation of Drugs Made From Biotechnology'' was issued in November 1995. The report announced several initiatives to reduce the burden of FDA regulations on the biologics industry without reducing public health protection, including a proposal to remove the requirements in § 600.10(a) for a ''responsible head.'' The proposed revision, reflecting comments submitted in response to the January 26, 1995, public meeting, would enable firms to designate more than one person to communicate directly with FDA on official matters related to the biological products they manufacture. The commitment to remove requirements for a ''responsible head'' was based on FDA's determination that, with the many changes that have occurred in science, technology, and corporate structure, it no longer may be practical for most biologics manufacturers to rely on one individual to meet the requirements included in § 600.10(a). In addition, the responsible corporate officer doctrine, e.g., *United States* v. *Park*, 421 U.S. 658 (1975); *United States* v. *Dotterweich*, 320 U.S. 277 (1943),

places the burden of ensuring compliance with the statutes and regulations applicable to biological products on corporate officials ''standing in responsible relation to a public danger.'' (*Dotterweich*, 320 U.S. at 281.) Thus, it is not necessary to require manufacturers to designate a ''responsible head'' in order to enforce the duty responsible corporate officials have to implement measures to ensure that violations do not occur. (*Park*, 421 U.S. at 672.)

In accordance with a recent revision to the definition of ''manufacturer'' in § 600.3 (see 61 FR 24227, May 14, 1996), a biologics applicant may apply for and obtain a license for a product to be manufactured at more than one manufacturing site that may or may not be owned by the applicant. Therefore, firms may want to designate more than one person with primary responsibility to maintain adequate oversight of multiple manufacturing sites and ensure that each is conforming to FDA's requirements for current good manufacturing practices and the applicable biologics standards. Many biologics manufacturers also manufacture drugs that are regulated by the Center for Drug Evaluation and Research (CDER) under the Federal Food, Drug, and Cosmetic Act whose regulations do not contain an analogous requirement for the responsible head. FDA's proposal to revise the requirements with respect to a responsible head is an effort to harmonize CBER's and CDER's policies and requirements and to keep pace with changes in science, technology, and corporate structure.

II. Proposed Rule

Under the proposed revision, an authorized official would be chosen by the applicant to receive and send correspondence to CBER. The applicant could choose to have more than one authorized official. Accordingly, the agency proposes to amend § 600.10 by removing and reserving paragraph (a) and revising the heading of paragraph (b) to read ''Personnel''. The agency also proposes to amend § 601.2 *Applications for establishment and product licenses; procedures for filing* by adding the statement ''The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application'' in paragraph (a) and new paragraph (c)(6). Finally, the agency proposes to amend § 601.25(b)(3)(VIII) by replacing ''signed by the responsible head (as defined in § 600.10 of this chapter of the licensee)'' with ''signed by an authorized official of the licensee''.

FDA is also proposing to remove § 606.20(a), which contains language similar to that in § 600.10(a) and applies to all blood establishments, including registered, unlicensed blood establishments. Like other components of the biologics industry, the blood industry has experienced changes in science, technology, and corporate structure. Complex donor and transfusion recipient issues, the evolution of sophisticated computerized laboratory and donor equipment, complicated serology problems, and state-of-the-art laboratory techniques have all contributed to changes within the structure of blood establishments, regardless of size. To ensure the quality and safety of the blood supply, many blood establishments employ personnel who are experts in donor issues, infectious disease, computers, molecular biology, serology, transfusion issues, quality control, administration, and management. It is no longer practical to expect one individual to have expertise in all the subspecialties of transfusion medicine. Accordingly, to provide sufficient flexibility for a blood establishment to select a person with appropriate training and experience to be responsible for each facet of its operation, the agency proposes to remove and reserve § 606.20(a).

FDA intends that a final rule would become effective as soon as possible after publication in the Federal Register.

III. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule would have no compliance costs and would not result in any new requirements. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

IV. 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.

Interested persons may, on or before April 29, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 606

Blood, Labeling, Laboratories, 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, it is proposed that 21 CFR parts 600, 601, and 606 be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361, 2125 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25).

§ 600.10 [Amended]

2. Section 600.10 *Personnel* is amended by removing and reserving

paragraph (a) and by revising the heading of paragraph (b) to read ''*Personnel.*''

PART 601—LICENSING

3. 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).

4. Section 601.2 is amended by adding a sentence before the last sentence in paragraph (a), and by adding new paragraph (c)(6) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) * * * The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. * * *

* * * * *

(c) * * *

(6) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application.

5. Section 601.25 is amended by revising the first sentence of paragraph (b)(3)(VIII) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * *

(b) * * *

(3) * * *

(VIII) If the submission is by a licensee, a statement signed by an authorized official of the licensee shall be included, stating that to the best of his or her knowledge and belief, it includes all information, favorable and unfavorable, pertinent to an evaluation of the safety, effectiveness, and labeling of the product, including information derived from investigation, commercial marketing, or published literature. * * *

* * * * *

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

6. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374); secs. 215, 351, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263a, 264).

§ 606.20 [Amended]

7. Section 606.20 *Personnel* is amended by removing and reserving paragraph (a).

Dated: January 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–2238 Filed 1–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Parts 404 Through 407

Seaway Regulations and Rules: Great Lakes Pilotage Regulations; Public Meeting

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Public meeting.

SUMMARY: This document announces a public meeting that will be held from 10 a.m. until 3 p.m., on March 11, 1997, in the Lambert Room at the Sheraton Airport Hotel at Cleveland Hopkins Airport in Cleveland, Ohio. The purpose of the meeting is to gather information and to provide a forum for members of the public to discuss their ideas for improving the safety, reliability and efficiency of the Great Lakes Pilotage System.

DATES: The public meeting will be held from 10 a.m. until 3 p.m., on March 11, 1997.

ADDRESSES: The public meeting will be held in the Lambert Room at the Sheraton Airport Hotel at Cleveland Hopkins Airport, 5300 Riverside Dr., Cleveland, OH 44135, phone (216) 267–1500.

FOR FURTHER INFORMATION CONTACT: Scott A. Poyer, Chief Economist, Saint Lawrence Seaway Development Corporation, Office of Great Lakes Pilotage, United States Department of Transportation, 400 7th Street SW., Suite 5424, Washington, DC 20590, phone 1–800–785–2779.

SUPPLEMENTARY INFORMATION: On September 25, 1996, the Saint Lawrence Seaway Development Corporation (SLSDC) published a notice of proposed rulemaking and hearing in the Federal Register (61 FR 50258) (the NPRM), which proposed to increase Great Lakes pilotage rates. In response to the NPRM and public hearing, the SLSDC received many comments which were beyond the scope of the NPRM. Many commenters recommended changes to the entire system of pilotage on the Great Lakes.

The current system of pilotage on the Great Lakes was established by the Great Lakes Pilotage Act of 1960 (46 U.S.C. Chapter 93), and its attendant Great Lakes Pilotage Regulations (33 CFR Parts 404–407). In the 36 years since the Great Lakes pilotage system was established the pilotage system has remained virtually unchanged, even though the maritime industry on the Great Lakes has changed substantially. Many commenters on the NPRM raised questions concerning the current pilotage system's safety, reliability and efficiency. These commenters, representing all facets of the maritime industry on the Great Lakes, requested a comprehensive review of this issue.

The purpose of the public meeting announced in this notice is to provide a forum for the public to discuss with the SLSDC, and with each other, ideas for improving the safety, reliability, and efficiency of the Great Lakes Pilotage System.

Issued at Washington, D.C. on January 23, 1997.

Saint Lawrence Seaway Development Corporation.

Gail C. McDonald,

Administrator.

[FR Doc. 97–1993 Filed 1–28–97; 8:45 am]

BILLING CODE 4910–61–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–26, RM–8968]

Radio Broadcasting Services; Detroit, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Great Plains Radiocasting requesting the allotment of Channel 294C2 at Detroit, Texas, as the community's first local FM service. Channel 294C2 can be allotted to Detroit in compliance with the Commission's minimum distance separation requirements with a site restriction of 22.0 kilometers (13.7 miles) northwest in order to avoid a short-spacing conflict with the licensed operation of Station KWSK(FM), Channel 295A, Daingerfield, Texas, at coordinates 33–49–16 NL; 95–24–16 WL.

DATES: Comments must be filed on or before March 17, 1997, and reply comments on or before April 1, 1997.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In