(bushing not installed), Option III, or Condition 2 (bushing installed), Option II, of the service bulletin, as applicable. And

(ii) Prior to the accumulation of 18,000 total landings on the pylon truss fitting following accomplishment of the modification, perform an ultrasonic inspection to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, in accordance with the service bulletin. And

(iii) Thereafter, repeat the ultrasonic inspection at intervals not to exceed 10,000 landings on the pylon truss fitting.

(3) If any crack is found in the pylon truss fitting during any inspection required by this paragraph, prior to further flight, repair it in accordance with the service bulletin. At the times specified in the service bulletin, perform follow-on actions in accordance with the service bulletin. In all cases, where the service bulletin indicates ''contact Douglas for disposition,'' the repair must be accomplished in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on September 21, 1995.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23913 Filed 9–26–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 95N–0295]

Prominence of Name of Distributor of Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the labeling regulations to remove the requirement that the manufacturer's name be more prominent than the distributor and to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling. This proposed change in the labeling requirements is intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements, and to harmonize labeling regulations applicable to biologic products licensed under the Public Health Service Act with the corresponding labeling regulations applicable to drugs approved under the Federal Food Drug and Cosmetic Act (the act). FDA is considering further revisions to the labeling requirements.

DATES: Comments by December 26, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson or Tracey Forfa, Center for Biologics Evaluation and Research (HFM–630), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is being issued in accordance with the principles set forth in Executive Order 12866 and the steps described in President Clinton's memorandum of March 4, 1995, announcing his ''Regulatory Reinvention Initiative.'' Executive Order 12866 directs Federal agencies and the Office of Information and Regulatory Affairs to implement measures that will reform and streamline the regulatory process. President Clinton's memorandum of March 4, 1995, sets forth four steps toward regulatory reform, one of which instructs agencies to revise those regulations that are in need of reform. FDA believes that this regulation is in keeping with these principles without compromising the agency's commitment to protect the public health.

Under Executive Order 12866, FDA published a notice in the Federal Register of January 20, 1994 (59 FR 3043), announcing FDA's plan to review and evaluate all significant regulations for their effectiveness in protecting the public health, while avoiding an unnecessary regulatory burden. In the Federal Register of June 3, 1994 (59 FR 28821 and 28822), FDA published two notices announcing the review and evaluation of certain biologic and blood and blood product regulations by the Center for Biologics Evaluation and Research (CBER). The intent of the review and evaluation was to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary.

FDA held a public meeting on January 26, 1995, that was announced in the Federal Register on January 9, 1995 (60 FR 2351). The public meeting was a forum for the public to voice comments regarding the review and evaluation of regulations being undertaken by CBER.

Some of the comments from the public meeting held to discuss the CBER regulations review questioned the need for the manufacturer's name to be the most prominent name on the label. Requests were made asking that CBER consider revising the labeling regulations so that developers of innovative new products would be able to have their names on the label, even if they contract out the manufacturing of the product. The labeling regulation addressing the name of the selling agent or distributor (§ 610.64 (21 CFR 610.64)), currently requires that the name of the manufacturer of the biological product be more prominently displayed on the label than the name of the selling agent or distributor. FDA announced its intention to issue a proposed rule to revise § 610.64 in the April 1995 National Performance Review Report, ''Reinventing Regulation of Drugs and Medical Devices.'' FDA made a commitment to issue the proposed rule within 6 months of the report.

II. The Proposed Rule

The proposed rule is intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements. FDA recognizes that small innovator firms may not have the facilities to manufacture commercial quantities of the product. Such innovator firms want the flexibility to contract out part or all of the manufacturing steps without being required to feature the product manufacturer's name more prominently on the label. In some cases manufacturers and distributors would prefer to have the option and the freedom to negotiate with each other for the prominence of the various firm names on the label.

The proposed rule is also intended to reduce the regulatory burden on manufacturers who produce both biologics and other drugs by harmonizing this labeling requirement with the labeling provisions approved

under the act (21 CFR 201.1), applicable to drugs.

The proposed rule removes the requirement that the manufacturer's name be more prominent than the distributor's name. The proposed rule permits a number of options for identifying the distributor so that the identification on the label may be consistent with the actual circumstances of the sale and distribution of the product. In cases where a distributor is named on the label, the proposed rule would require the use of a qualifying phrase to distinguish the manufacturer and distributor of the product. The requirement that the name, address, and license number of the manufacturer also appear on the container label (21 CFR 610.60) and package label (21 CFR 610.61) would remain unchanged.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(d)(10) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 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.

FDA has assessed the economic impact of the proposed rule under the Regulatory Flexibility Act. Under the Regulatory Flexibility Act, FDA must analyze regulatory options that would minimize any significant impact of the rule on small entities. This amendment does not require any entity to change its current procedures. At this time FDA cannot quantify the benefits of the rule. However, it may benefit manufacturers or distributors by allowing greater flexibility in labeling. The amendment provides labeling alternatives by allowing the names of distributors to be as (or more, or less) prominent than names of manufacturer(s) on the label. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1980

This rule removes an unnecessary labeling requirement. The immediate effect of the rule allowing names of distributors to be as prominent as names of manufacturers is neutral. The rule does not require any changes in current labels. Accordingly, Office of Management and Budget clearance is not required under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq*.).

VI. Request for Comments

Interested persons may, on or before December 26, 1995, 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.

Lists of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

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, it is proposed that 21 CFR part 610 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, and 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).

2. Section 610.64 is revised to read as follows:

§ 610.64 Name and address of distributor.

The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: ''Manufactured for ————————'', ''Distributed by ————————'', ''Manufactured by ———————— for ————————'', ''Manufactured for ———————— by ————————'', ''Distributor: ————————'', or ''Marketed by ————————'' . The qualifying phrases may be abbreviated.

Dated: September 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–23997 Filed 9–26–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 311

OSD Privacy Program

AGENCY: Office of the Secretary of Defense, DOD.

ACTION: Proposed rule.

SUMMARY: In accordance with the Privacy Act of 1974, the Office of the Joint Staff proposes to exempt the system of records JS004SECDIV, entitled Joint Staff Security Clearance Files. The exemption is needed to comply with prohibitions against disclosure of information provided the government under a promise of confidentiality and to protect privacy rights of individuals identified in the system of records.

DATES: Comments must be received no later than November 27, 1995 to be considered by this ageny.

ADDRESSES: Send comments to OSD Privacy Act Officer, Directives and Records Division, Washington Headquarters Services, Correspondence and Directives, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Cragg at (703) 695–970.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Director, Administration and Management, Office of the Secretary of Defense has determined that this proposed Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).