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).

Regulatory Flexibility Act of 1980.

The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act.

The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act proposed rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

Investigative and other records needed to make the judgment of approval or denial of a security clearance may require that certain records in the system be protected using the specific exemption (k)(5), to insure that a source who furnished information to the Government under an express promise of confidentiality be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence will be afforded such protection.

List of Subjects in 32 CFR part 311

Privacy.

Accordingly, 32 CFR part 311 is amended as follows:

1. The authority citation for 32 CFR part 311 continues to read as follows:

Authority: Pub. L. 93-579, 88 Stat 1896 (5 U.S.C. 552a).

2. Section 311.7 is amended by adding paragraph (c)(9) as follows:

§ 311.7 Procedures for exemptions.

* * * * *

(c) *Specific exemptions.* * * *

(9) *System identifier and name*--JS004SECDIV, Joint Staff Security Clearance Files.

Exemption. Portions of this system of records are exempt pursuant to the provisions of 5 U.S.C. 552a(k)(5) from subsections 5 U.S.C. 552a(d)(1) through (d)(5).

Authority. 5 U.S.C. 552a(k)(5).

Reasons. From subsections (d)(1) through (d)(5) because the agency is required to protect the confidentiality of sources who furnished information to the government under an expressed promise of confidentiality or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. This confidentiality is needed to maintain the Government's continued access to information from persons who otherwise might refuse to give it. This exemption is limited to disclosures that would reveal the identity of a confidential source. At the time of the request for a record, a determination will be made concerning whether a right, privilege, or benefit is denied or specific information would reveal the identity of a source.

* * * * *

Dated: August 22, 1995.

Linda L. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–23943 Filed 9–26–95; 8:45 am]

BILLING CODE 5000–04–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AK10–1–7022b; FRL–5287–6]

Approval and Promulgation of State Implementation Plans: Alaska

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve most of the Alaska State Implementation Plan (SIP) revision for the inclusion of transportation and general conformity rules to ensure that Federal actions conform to the appropriate SIP and take no action on the remaining small portion of it. The SIP revision was submitted by the State to satisfy EPA regulation requirements. In the final rules section of this Federal Register, the EPA is approving most of the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this action.

DATES: Comments on this proposed rule must be received in writing by October 27, 1995.

ADDRESSES: Written comments should be addressed to MontelLivingston, Air Programs Section, at the EPA Regional Office listed.

Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Air Programs Section (AT–082), 1200 6th Avenue, Seattle, WA 98101.

The State of Washington Department of Ecology, P.O. Box 47600, Olympia, WA 98504.

FOR FURTHER INFORMATION CONTACT: Kelly Huynh, Air Programs Section (AT–082), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553–1059.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the rules section of this Federal Register.

Dated: August 18, 1995.

Charles Findley,

Acting Regional Administrator.

[FR Doc. 95–23842 Filed 9–26–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 52

[VA21–1–5883b; FRL–5292–3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia—VOC RACT Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia on November 6, 1992. This revision pertains to amendments to Virginia's major source volatile organic compound (VOC) reasonably available control technology (RACT) requirements. In the Final Rules section of this Federal Register, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are