for human error afforded by the process of cutting, sorting, and subsequent handling of different items of labeling from gang-printed materials that has caused labeling mixups and recalls. One of the goals of this proposed rulemaking is to reduce the likelihood for such human error through the use of automated labeling control systems.

III. Environmental Impact

The agency has determined under 21 CFR 25.24 (a) (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, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (2 U.S.C. 1532). 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.

The proposed rule substantially reduces the scope of the 1993 final rule, which applied to all cut labeling, so that the proposed rule only applies to cut labeling for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. This proposed rule also increases flexibility for firms selecting special labeling control procedures by adding a provision for the use of any automated technique, including differentiation by size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment. Therefore this proposed rule is expected to have a positive economic impact on drug manufacturers that would otherwise be subject to the more stringent requirements under current regulations.

Mislabeled drug products may pose a threat to public health, lead to extremely costly product recalls, and create significant product liability. As a result, FDA believes that a large number of firms already use the labeling control procedures proposed in this rulemaking. The agency concludes that the proposed rule is not a major rule as defined in Executive Order 12866 because the labeling control revisions significantly reduce the scope of the current rule and provide manufacturers with greater flexibility in selecting special control procedures if cut labeling is used. Further, the agency certifies that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act.

The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). Because this proposed rule will not impose a cost of $100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

V. Request for Comments

Interested persons may, on or before October 27, 1997, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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 in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 211 be amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 211.122 is amended by revising the introductory text of paragraph (g) and by adding new paragraph (g)(4) to read as follows:

§ 211.122 Materials examination and usage criteria.

* * * * *

(g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures:

* * * * *

(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

* * * * *

Dated: July 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19817 Filed 7-28-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AI84

Grants to States for Construction or Acquisition of State Home Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the ''Medical'' regulations in 38 CFR part 17 regarding applications for grants to States for the construction or acquisition of State home facilities. VA awards grants based on a priority ranking system. Usually, the higher priority applications deplete the available funding to the extent that the lowest ranking application to be offered funding is offered only a partial grant. It is proposed that if the lowest ranking grant application receives only a partial grant in a fiscal year and if such grant award is partial solely because VA has insufficient funds for a full grant, the application would be placed at the top of the list within its priority group for the next fiscal year. Often applicants are hesitant to accept a partial grant because of the uncertainty of receiving an additional grant the next fiscal year. It appears that the adoption of the proposal would encourage States to accept a partial grant by creating the likelihood that the State would receive an additional grant in the subsequent

fiscal year. Accordingly, this would help ensure that VA would be able to award grants to higher priority applicants that might otherwise reject partial funding.

Also, it is proposed that the applicant receiving partial funding and receiving priority as proposed would not be required to submit a second application for additional funds in the subsequent fiscal year, but could be required to update information already submitted. It appears that the first application would normally be adequate because the grant award in the second fiscal year would be for the same project which received the partial grant award.

Further, under the proposal, the total amount awarded for the application could not exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application. This is consistent with the statutory requirement that limits grant awards to no more than 65 percent of the estimated cost of construction or acquisition.

DATES: Comments must be received on or before September 29, 1997.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1154, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AI84.'' All written comments received will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Ms. Kathleen Greve, Geriatrics and Extended Care Strategic Healthcare Group, (202) 273–8534.

SUPPLEMENTARY INFORMATION: The Secretary hereby certifies that the adoption of this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The rule would affect grants to States and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule would be exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program number for this document is 64.005.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: July 17, 1997.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 17 is proposed to be amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follow:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. In § 17.212, paragraph (d) is added immediately before the section authority citation following paragraph (c) to read as follows:

§ 17.212 Scope of grants program.

* * * * *

(d)(1) Notwithstanding paragraph (c) of this section and the provisions for ranking projects within a priority group in § 17.213(c)(3)(i), the Secretary shall give an application first priority within the priority group to which it is assigned on the list of projects established under § 17.213(d) for the next fiscal year if:

(i) the State has accepted a grant for that application as of August 15 of the current fiscal year that is less than the amount that the Secretary would have awarded if VA had had sufficient grant funds to award the grant in such amount in that fiscal year; and

(ii) the application is the lowest ranking application on the priority list for the current fiscal year for which grant funds are available as of August 15 of that year.

(2) The Secretary shall not require a State to submit a second grant application for a project which receives priority under paragraph (1) of this section but may require the State to update information already submitted in the application for the project. The Secretary shall determine the amount of a second grant at the time of the award of that grant. In no case shall the total amount awarded for the application exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application.

* * * * *

[FR Doc. 97–19855 Filed 7–28–97; 8:45 am]

BILLING CODE 8320–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN189–1–9730(b); TN194–1–9731(b); TN198–1–9732(b); FRL–5859–6]

Approval of Revisions to the Tennessee SIP Regarding Prevention of Significant Deterioration and Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving miscellaneous revisions to the Tennessee State Implementation Plan (SIP) regarding prevention of significant deterioration (PSD) and volatile organic compounds (VOC). The revisions to the PSD regulation add an additional supplement to the EPA ''Guideline on Air Quality Models''. The revisions to the VOC regulation make minor changes to the regulation for the manufacture of high-density polyethylene, polypropylene and polystyrene resins and to the regulation containing test methods and compliance procedures for VOC sources. In the final rules section of this **Federal Register**, the EPA is approving the submitted chapter in its entirety as a direct-final rule without prior proposal because the EPA views this as a noncontroversial 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 received in response to this proposed rule, no further activity is contemplated in relation to this proposed rule. If 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 document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by August 28, 1997.

ADDRESSES: Written comments on this action should be addressed to William Denman at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW,