1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT:

Wade Carpenter, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–ASO–10.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposed contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contract with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class E airspace area at Anniston, AL. GPS RWY 3 and RWY 15 SIAPs have been developed for Talladega Municipal Airport, and a GPS RWY 20 SIAP has been developed for St. Clair County Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate these SIAPs, and for IFR operations at these airports and the Anniston Metropolitan Airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

ASO AL E5 Anniston, AL [Revised]

Anniston Metropolitan Airport, AL
(lat. 33°35′17″ N, long. 85°51′29″ W)
Talladega Municipal Airport
(lat. 33°34′12″ N, long. 86°03′04″ W)
St. Clair County Airport
(lat. 33°33′32″ N, long. 86°14′57″ W)

That airspace extending upward from 700 feet above the surface within a 12-mile radius of Anniston Metropolitan Airport and within a 9.5-mile radius of Talladega Municipal Airport and within a 11.5 mile radius of St. Clair County Airport, excluding that airspace within Restricted Area R–2101 when the restricted area is active.

* * * * *

Issued in College Park, Georgia, on July 15, 1997.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–19859 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 97N–0300]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the packaging and labeling control provisions of the current good manufacturing practice (CGMP) regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. FDA is also proposing to permit the 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 when cut labeling is used. This action is intended to protect consumers from labeling errors more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. This action is also intended to permit manufacturers to use a broader range of error prevention and labeling control techniques.

DATES: Comments by October 27, 1997. FDA proposes that any final rule that may issue based on this proposal become effective 6 months after its date of publication in the **Federal Register**.

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

FOR FURTHER INFORMATION CONTACT:

Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), 5600 Fishers Lane, Rockville, MD 20857, 301–594–5621 (Internet electronic mail: kuchenbergt@cder.fda.gov); or

Paul J. Motise, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1089 (Internet electronic mail: motise@cder.fda.gov).

SUPPLEMENTARY INFORMATION:

I. Background

Persistent problems with drug product mislabeling and subsequent recalls in the late 1980's led FDA to review labeling procedures and product recalls. The review identified gang-printed or cut labeling as a leading cause of labeling mixups. Gang-printed labeling is defined in 21 CFR 210.3(b)(22) as labeling derived from a sheet of material on which more than one item of labeling is printed. Each sheet includes labeling for a variety of products and, because of this, labeling for individual drug products must be ''cut'' or separated from the labeling for other products. Cut labeling for individual drug products is commonly placed in separate stacks before being transported to packaging and labeling lines for application to appropriate products. FDA found that stacks of labeling of similar size, shape, and color could easily be intermixed and, if the error was not detected by the printer or manufacturer, incorrect labeling could be applied and a mislabeled drug product distributed.

To reduce the frequency and likelihood of such mislabeling, FDA, in the **Federal Register** of August 3, 1993 (58 FR 41348), amended the packaging and labeling control provisions of the CGMP regulations in part 211 (21 CFR part 211) to provide specific conditions for the use of all gang-printed or cut labeling (hereinafter referred to as the 1993 final rule). Under § 211.122(g), packaging and labeling operations must use one of three special control features if cut labeling is used. Packaging and labeling lines must be dedicated to each different strength of each different drug product, appropriate electronic or electromechanical equipment must be used to conduct a 100-percent examination for correct labeling during or after completion of finishing operations, or, where labeling is hand-applied, a 100-percent visual inspection must be conducted by one person and independently verified by a second person. Appropriate electronic or electromechanical equipment typically consists of systems that scan identity codes printed on the labeling. If the wrong code is detected, the incorrect labeling is ejected from the labeling line.

To further limit the potential for mislabeling, FDA also required written procedures for the identification and handling of filled drug product containers not immediately labeled (§ 211.130(b)). FDA also amended § 211.125(c) to exempt manufacturers that use automated 100-percent examination for correct labeling from the label reconciliation requirements.

The 1993 final rule applied to all types of labeling including product inserts, multiunit containers packaged in individual containers, and shipping containers.

In May 1994, FDA received two citizen petitions from several trade associations requesting that the agency extend the effective date of the rule and reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling other than the immediate container label. The petitions stated that additional time was needed to obtain, install, or validate equipment necessary to comply with the rule. The citizen petitions also contended that the final rule inappropriately expanded the scope of § 211.122(g) from immediate container labels to all drug product labeling.

In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA extended the compliance date for § 211.122(g) as it applies to labeling other than immediate container labels, and opened the administrative record through October 4, 1994, for comments on the scope of § 211.122(g). All other provisions of the final rule became effective on August 3, 1994. FDA further extended the compliance date to August 2, 1996, in the **Federal Register** of April 28, 1995 (60 FR 20897), and to August 1, 1997, in the **Federal Register** of July 19, 1996 (61 FR 37679).

Elsewhere in this issue of the **Federal Register**, FDA is announcing a continuation of the partial extension of the compliance date until the effective date of the regulation finalizing this proposed rule.

FDA received 14 comments during the extended comment period. Those comments that addressed the scope of § 211.122(g) are discussed below:

Concerning the question of whether § 211.122(g) should be applied to items of labeling other than the immediate container label, most comments favored restricting application of the regulation either to immediate container labels or to some category or subset of overall product ''labeling.'' Several comments requested that manual differentiation by size, shape, and color as well as other validated labeling control methods be added to the list of special control procedures listed in § 211.122(g). One comment asserted that specifying the use of electronic or electromechanical methods as a special control procedure unnecessarily limits the options of firms packaging pharmaceuticals. A number of comments stated that, with appropriate controls, the use of size, shape, or color differentiation as a manual labeling control measure is adequate to prevent labeling mixups. A number of comments asked for clarification as to which types of cut labeling would require the use of an automated verification system. Some comments requested exemptions for specific labeling. One comment requested that hand-labeling operations be specifically excluded from the requirement for electronic inspection, regardless of the volume of the manufacturing operation, if labeling is inspected manually. Another comment recommended procedures to be used when cut labeling is applied to dosage-form packages assembled in stages.

In light of comments received during the extended comment period, FDA held a number of meetings with representatives of the labeling industry and others to examine control options available through current technology.

After evaluating the comments, reviewing the recall data, and surveying packaging and labeling control technology, FDA has determined that the scope of § 211.122(g) should be

narrowed and the permissible control procedures expanded. FDA is proposing to limit the scope of the cut labeling provision to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. FDA is also proposing to expand the permissible control procedures to include the 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.

II. Description of the Proposed Rule

A. Scope

The first sentence of current § 211.122(g) states: ''If cut labeling is used, packaging and labeling operations shall include one of the following special control procedures''.

FDA is proposing to limit the scope of § 211.122(g) by revising this sentence to state: ''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''.

FDA's main concern in proposing controls for cut labeling is to reduce the public health and safety risk stemming from drug product labeling mixups. The petitions and comments on the scope of § 211.122(g) asserted that the economic burden on industry would be great if the provision applied to all labeling, and questioned whether including such types of labeling as shipping cartons, that are unlikely to be read by consumers, would provide any significant additional protection to public health and safety.

FDA has examined these comments and other information and agrees that the greater the likelihood that consumers will read incorrect labeling information, the greater the danger that the drug product will be used according to the mislabeled instructions. Thus, the immediate container label poses the most obvious threat. In addition, individual unit carton labeling could pose an equal danger because it is the outermost container in which a drug product is commonly marketed at retail and many consumers read this labeling when deciding whether to purchase a product. Moreover, because the individual unit carton labeling may be in a larger type or otherwise easier to read than the immediate container label, consumers may keep the carton and refer to it when using the drug product. A similar concern applies to multiunit cartons containing immediate containers that are not packaged in individual unit cartons (e.g., sterile dosage forms in tray packs in which immediate containers lack unit cartons), because consumers and health professionals are more likely to rely on labeling on the outer multiunit container than to examine the labeling on the individual drug product immediate containers. In deciding whether to limit the scope of the labeling control provisions, FDA reviewed recall data to determine the danger to consumers from errors in different types of drug product labeling.[1] This examination indicated that there have been Class I and Class II recalls involving immediate containers, individual unit cartons containing the drug product in its immediate container, and multiunit cartons containing immediate containers that are not packaged in individual unit cartons. Recalls due to the use of the wrong inserts or outserts (printed information about a drug product attached to the exterior of the product) and recalls of multiunit or shelf-pack containers holding unit cartons, shipping or intermediate containers, and shipping cases have all been designated as Class III recalls, i.e., situations in which the labeling error is generally not likely to cause adverse health consequences.

Therefore, FDA is proposing that the control procedures specified in § 211.122(g) apply only to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. This action is intended to protect consumers from labeling errors that are more likely to cause adverse health consequences, while eliminating the regulatory burden of applying the rule to labeling unlikely to reach or adversely affect consumers. The proposal is also intended to eliminate any confusion about the scope of the cut labeling control provisions and allow an additional opportunity for public comment.

Although a number of types of labeling would not be subject to this proposed rule, it is important to note that any labeling mixup can result in a misbranded drug product. FDA encourages manufacturers to take steps to protect the integrity of their labeling operations. Although not proposed in this rulemaking, FDA encourages firms to: (1) Convert all articles of cut labeling to roll labeling where possible (such as the use of roll inserts or roll label/insert combinations); (2) use online printing methods; or (3) adopt 100-percent automated verification systems for all items of cut labeling.

B. Special Control Procedures

Under § 211.122(g)(1), (g)(2), and (g)(3), packaging and labeling operations must include one of the following special control procedures when cut labeling is used: (1) Dedication of labeling and packaging lines to each different strength of each different drug product; (2) use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or (3) use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling.

FDA is proposing to add a fourth special control procedure at § 211.122(g)(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.'' FDA is proposing this additional control procedure because the agency believes that a number of other automated techniques will also physically prevent incorrect labeling from being processed by packaging and labeling equipment, and would provide manufacturers with the widest possible latitude in selecting appropriate labeling control technologies. A labeling control method using size and shape as part of an automated technique that prevents incorrect labeling from being processed by labeling and packaging lines provides the same labeling control protection, through prevention, as do the other special control procedures through surveillance or dedication of labeling and packaging lines. An acceptable automated technique would allow labeling and packaging operations to operate only if correct labeling unique to a given product (e.g., a specific size) is used.

FDA notes, however, that nonautomated (i.e., manual) differentiation of size and shape as a labeling control does not provide adequate protection from labeling mixups. It is the increased opportunity

[1] Unless ordered by a court, a drug recall is a voluntary action whereby manufacturers remove from the market drugs that are found by FDA to be marketed in violation of laws administered by the agency.

Under FDA's current policy, the agency assigns a numerical designation to each product recall to indicate the relative degree of hazard presented by the product being recalled. A Class I recall involves the greatest potential health threat and a Class III recall involves the least serious health threat.

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