(2) *Receipt of an application* means the date on which the Commission receives the application or an amendment allowed for good cause shown and the applicable filing fee, if any; and

* * * * *

§ 365.5 Amendment of Applications.

The Commission will allow amendments of applications for good cause shown without payment of additional filing fees. If the amendment is accepted, notice of the amended application will be published in the Federal Register, with further opportunity for comments.

PART 375—THE COMMISSION

1. The authority citation for part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

2. In § 375.309, paragraph (g) is revised to read as follows:

§ 375.309 Delegations to the General Counsel.

* * * * *

(g) Grant uncontested applications for exempt wholesale generator status that do not involve unusual or interpretation issues; to act on uncontested motions to withdraw such applications; and to act on uncontested amendments to applications for EWG status that do not present unusual or interpretation issues.

[FR Doc. 96–28476 Filed 11–5–96; 8:45 am]

BILLING CODE 6717–01–P

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the labeling regulations for biological products to remove the requirement that the manufacturer's name be more prominent than that of the distributor and to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling. This change in 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 (the PHS Act) with the corresponding labeling regulations for drugs approved under the Federal Food, Drug, and Cosmetic Act (the act).

EFFECTIVE DATE: November 18, 1996.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of September 27, 1995 (60 FR 49811), FDA published a proposed rule to amend the labeling regulations to remove the requirement that the manufacturer's name be more prominent than the distributor's and to permit the names of distributors to be prominently displayed on licensed biological product container labels, package labels, and labeling. This final rule is being issued in accordance with the principles set forth in Executive Order 12866 and the Regulatory Reinvention Initiative announced in President Clinton's memorandum of March 4, 1995. 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. As part of the Regulatory Reinvention Initiative, a report entitled ''Reinventing Drug and Medical Device Regulations'' was issued in April 1995 by the President and Vice President. This final rule completes a commitment made by FDA in that report to permit greater flexibility in the appearance of distributors' names on biological product container labeling, package labels, and labeling.

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 achieving public health goals and in order to reduce or eliminate unnecessary regulatory burden. In the Federal Register of June 3, 1994 (59 FR 28821 and 28822, respectively), 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. Interested persons were given until August 17, 1994, to respond to the notices by submitting written comments to the Dockets Management Branch. In the Federal Register of August 17, 1994 (59 FR 42193), FDA extended the comment periods to November 15, 1994, in response to requests to allow for additional time for public comment. In the Federal Register of November 14, 1994 (59 FR 56448), FDA extended the comment periods to February 13, 1995, in response to requests to hold a public meeting regarding the biologics regulations under review.

FDA held a public meeting on January 26, 1995, that was announced in the Federal Register of January 9, 1995 (60 FR 2351). The notice of public meeting indicated that the public comment period was to close on February 13, 1995. The public meeting was a forum for the public to voice their comments regarding the review and evaluation of regulations being undertaken by CBER.

Some of the comments from the docket and public meeting questioned the need for the manufacturer's name to be the most prominent name on the label of a licensed biological product. FDA's regulation addressing the name of the selling agent or distributor on biological product labeling (§ 610.64 (21 CFR 610.64)) required 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. These comments requested that CBER consider revising the labeling regulations so that developers of innovative new products could place their names prominently on the label, even if they contract out the manufacturing of the product. In response to the comments, FDA published a proposed rule (60 FR 49811) to amend the labeling regulations to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling.

II. Highlights of the Final Rule

The final 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 a biological product. Such innovator firms that do not hold the license for the product will no longer be required to feature the license holder's name more prominently on the label. Manufacturers and distributors will have the option to

negotiate with each other for the prominence of the various firm names on the label.

The final 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 in § 201.1 (21 CFR 201.1) applicable to drugs approved under the act.

The final rule removes the requirement that the manufacturer's name be more prominent than the distributor's name on product labeling. The final rule prescribes a number of options for identifying the distributor so that the information on the label is consistent with the actual circumstances of the sale and distribution of the product. In cases where a distributor is named on the label, the final rule requires the use of a qualifying phrase to distinguish the manufacturer and distributor of the product. The requirements 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) remain unchanged.

III. Comments on the Proposed Rule and FDA Responses

FDA received five letters of comments on the proposed rule. All of the letters were from biological product manufacturers and distributors. All letters favored the proposed rule. Two comments requested that the proposed rule be broadened to further harmonize the biologics labeling regulations with requirements applicable to drugs approved under the act. One comment requested clarification of the proposed rule.

1. One comment requested that FDA completely harmonize § 610.64 with § 201.1 regarding appearance of the manufacturer's name and address. The comment stated that FDA's proposal to retain the requirement that the manufacturer's name and address appear on the label of a biologic product imposes regulatory burden on manufacturers who produce both biological products and drugs approved under the act, as there is no such corresponding requirement for drugs subject to § 201.1.

FDA agrees that harmonizing the labeling requirements applicable to biological products with those applicable to drugs approved under the act is desirable, where appropriate. The PHS Act, section 351(a), requires that each package of a biological product subject to licensure be plainly marked with the name, address, and license number of the manufacturer. The agency believes that the provision in this final rule that the manufacturer's name, address, and license number must appear on the label of a biological product is a reasonable approach to address the statutory requirement. However, as part of the May 14, 1996 (61 FR 24227), final rule to eliminate the establishment license application requirement for specified biotechnology and specified synthetic biological products licensed under the PHS Act, FDA has broadened the definition of ''manufacturer'' in 21 CFR 600.3(t) to provide greater flexibility in determining who may hold a license, and consequently, who would be identified as the ''manufacturer'' in labeling.

2. A second comment requested that FDA clarify whether the deletion of the requirement that a distributor's name be less prominent than the manufacturer's name would apply to promotional labeling.

While the final rule applies by its terms to the ''label'' on a biological product and does not specifically address promotional labeling, FDA intends to apply a similar policy in its review of promotional labeling.

3. A third comment asked that consideration be given to allowing the product trademark or logo to appear on the labeling in larger type than the product name.

The requirement that the proper name be at least as prominent as the trademark and trade name is included in 21 CFR 610.62. Labeling requirements other than in § 610.64 are not addressed in this rulemaking. In the Federal Register of June 3, 1994 (58 FR 28821), FDA announced that it was undertaking the review of the general biologics and licensing regulations, including labeling regulations. FDA will consider the comment regarding the prominence of the product trademark or logo as part of the general review of the regulations.

FDA has considered all comments received in response to the proposed rule and has determined that the proposed rule should be issued as a final rule. Accordingly, FDA is issuing as a final rule a revised § 610.64 to provide greater flexibility in displaying the prominence of the name of a product distributor on the product label.

IV. Effective Date

The final rule is effective November 18, 1996. As provided under 5 U.S.C. 553(d) and § 10.40(c)(4) (21 CFR 10.40(c)(4)), the effective date of a final rule may not be less than 30 days after date of publication, except for, among other things, ''a regulation that grants an exemption or relieves a restriction'' (§ 10.40(c)(4)(i)). Because, as described in section V. of this document, this final rule will provide greater flexibility in labeling to manufacturers and distributors of biological products, FDA believes that an effective date shorter than 30 days is appropriate.

V. Analysis of Impacts

FDA has examined the impact of the final 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 impact; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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, FDA must analyze regulatory options that would minimize any significant economic impact of the rule on small entities. This 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. It does not require any entity to change its current procedures. At this time FDA cannot quantify the benefits of the rule, although it may benefit manufacturers or distributors by allowing greater flexibility in labeling. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FDA certifies that this rule will not have a significant economic impact on a substantial number of small entities, and no further analysis is required.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(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.

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, 21 CFR part 610 is 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, 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 (41 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: October 28, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28530 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 640

[FHWA Docket No. 95–19]

RIN 2125–AD62

Certification Acceptance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA, in an interim final rule published in the Federal Register on September 13, 1995, adopted a policy that allows State highway agencies (SHAs) to use the certification acceptance (CA) procedures for non-Interstate projects to supplement the administrative flexibility provided in the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Public Law 102–240, 105 Stat. 1914. This final rule contains one minor modification to the CA policy to clarify that certain project actions do not require FHWA approval.

EFFECTIVE DATE: This regulation is effective December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Félix Rodríguez-Soto, Federal-Aid and Design Division, Office of Engineering, (202) 366–1564, or Mr. Wilbert Baccus, Office of the Chief Counsel, (202) 366–0780, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On September 13, 1995, the FHWA published an interim final rule (60 FR 47480) establishing the procedures to be followed by SHAs for the processing of transportation projects under CA. A 90-day period for agencies, firms, or individuals to provide comments was allowed. The changes made to the CA regulation by the interim final rule are discussed below.

The interim final rule eliminated the mandatory requirement for evaluation of the CA program in each State every four years. The requirement that the State's laws, regulations, directives, and standards must accomplish the policies and objectives contained in title 23, U.S.C., was retained. In keeping with the streamlining effort, specific requirements of the States for CA, including reports, were deleted because title 23, U.S.C., requirements will be subject to periodic changes. The revised CA regulation provided that States may be requested to furnish reports and information at the discretion of the FHWA. All references to the Secondary Road Plan (SRP) were removed because the SRP program was eliminated under the ISTEA restructuring.

The CA procedures were not completely eliminated because, even in light of the additional flexibility provided by the ISTEA and, in particular, 23 U.S.C. 106, National Highway System (NHS) projects may be administered under CA and may not be administered under 23 U. S. C. 106. In addition, some SHAs continue to use CA notwithstanding the more flexible options available under 23 U. S. C. 106.

Discussion of Comments

This section addresses the comments received on the interim final rule. The FHWA received comments from six SHAs and one organization.

General Comments

Five States supported the regulation (two as published in the interim final rule and three with minor modifications).

One State commented that CA has worked successfully in that State. This State was concerned that partial or full revocation by the FHWA of a State's CA plan could be based on process review findings which may not be part of a State's CA plan. This State also recommended that the final rule establish the nature of the process reviews and other evaluations and that an appeal process be established in case of partial or full revocation. In response, the FHWA maintains that the revisions to the CA regulation were meant to update the regulation to conform to new program provisions, to simplify the existing regulation by eliminating unnecessary and prescriptive requirements, and to allow for the use of process reviews which are already the primary form of program oversight by the FHWA. The use of process reviews is not unique for CA projects and the FHWA's methods of conducting process reviews should be familiar to SHA's. The States' right to appeal was not changed by the interim final rule.

The one organization that commented contends that an interim rule, without previous issuance of a notice of proposed rulemaking, inhibits public participation and debate on a proposed regulation and causes reliance by States on interim policy which may subsequently change as result of public comments. In addition, it alleges that the supplementary information section in the preamble to the interim rule, as published in the Federal Register (60 FR 47480), is inaccurate when it characterizes a State CA procedure as legally acceptable if it merely ''aims to comply'' with title 23, U. S. C., policies, and that ''streamlining'' of CA is a full retreat from Federal monitoring of the use of Federal highway construction dollars.

In response to this organization's contention concerning the use of an interim rule, the FHWA maintains that the interim rule merely updated the CA regulation, removed unnecessary prescriptive requirements as part of the government regulatory review effort, provided more administrative flexibility in the use of the regulation, and did not impose any additional restrictions on the public. The FHWA intends that a State accomplish title 23, U.S.C., policies through its CA procedures. The FHWA also maintains that the ''streamlining'' is not a ''retreat'' from FHWA oversight, but an acknowledgment that the use of process reviews and evaluations is the current and primary method of project oversight by the FHWA and that it accomplishes the same objective as the former project specific reviews. In addition, the