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Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 77N-0094]

RIN 0905-AA06

Drug Products for the Treatment and/or Prevention of Nocturnal Leg Muscle Cramps for Over-The-Counter Human Use; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of August 22, 1994 (59 FR 43234). The document established that any over-the-counter (OTC) drug product for the treatment and/or prevention of nocturnal leg muscle cramps is not generally recognized as safe and effective and is misbranded. The document was published with some typographical errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

In FR Doc. 94-20449, appearing on page 43234, the following corrections are made:

1. On page 43239, in the third column, in reference 3, line 5, and in reference 4, line 2, the word "Q-VELR" is corrected to read "Q-VEL®".

2. On page 43242, in the second column, line 21, and in the first full paragraph, line 19, the number "106" is corrected to read "10⁶".

3. On page 43245, in the second column, in reference 4, line 2, and in reference 5, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

4. On page 43249, in the second column, in reference 1, line 2, and in reference 2, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

5. On page 43250, in the third column, in reference 1, line 2, and in reference 2, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

6. On page 43252, in the first column, in the second paragraph, in line 2, "regulatuion" is corrected to read "regulation"; and in line 7, the word "agencies" is corrected to read "agency's"; and in line 8, the word "substances" is corrected to read "substance".

Dated: September 21, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94-24014 Filed 9-27-94; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 600, 610, 630, and 640

[Docket No. 93N-0392]

Biologics; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by substituting the term "supplement" for "amendment" when referring to the submission of a change to an approved establishment license or product license application. This action is being taken to harmonize the regulations with terminology used in the Prescription Drug User Fee Act of 1992.

DATES: Effective September 28, 1994; written comments by December 12, 1994.

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: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: The Prescription Drug User Fee Act of 1992 (Pub. L. 102-571) (section 735 (21 U.S.C. 379g)) defines the term "supplement" as "a request to the Secretary to approve a change in a human drug application which has been approved." Also in section 735 of the Prescription Drug User Fee Act, a "human drug application" includes "an application for licensure of a biological product under section 351 of the Public Health Service Act." FDA is amending the biologics regulations by substituting the term "supplement" for "amendment." This change is being made to harmonize the regulations with the terminology used in the Prescription Drug User Fee Act of 1992.

Prior to this announced change in terminology, the term "amendment" was used for all changes to both approved and unapproved license applications and amendments. In general, FDA intends to use the term "supplement" when referring to the submission of a change to an approved license application, and the term "amendment" when referring to the submission of a change to an unapproved license application or amendment. This change will not affect pending supplements (amendments) to establishment or product license applications.

This final rule contains only a minor change that is necessary to clarify terminology in the regulations. The rule change will not affect the way a license amendment or supplement to an application should be submitted to the agency, except in the way it is identified; nor will the change affect the way a license amendment or supplement will be reviewed by FDA. Therefore, FDA finds that there is good cause to dispense with a notice of proposed rulemaking as unnecessary, pursuant to the Administrative Procedure Act (5 U.S.C. 553) and FDA's administrative practices and procedures regulations (21 CFR 10.40(e)). FDA also finds, in accordance with the Administrative Procedure Act, that there is good cause to make this final rule effective on the date of publication in the **Federal Register**. FDA, however, is allowing 75 days for public comment on this final rule, in accordance with 21 CFR 10.40(e)(1).

Interested persons may, on or before December 12, 1994, submit to the Dockets Management Branch (address above) written comments regarding this rule. 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. FDA will consider any comments submitted to determine if any additional changes to the regulations are necessary.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.