Issued in Renton, Washington, on September 21, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–23815 Filed 9–27–94; 8:45 am]

BILLING CODE 4910–13–U

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 "10^6".

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.

21 CFR Part 630

Biologics, Labeling.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 600, 610, 630, and 640 are amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

§ 600.15 [Amended]

2. Section 600.15 *Temperatures during shipment* is amended in paragraph (b) by removing the words "an amendment" and by adding in their place the words "a supplement".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. 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 (42 U.S.C. 216, 262, 263, 263a, 264).

§ 610.9 [Amended]

4. Section 610.9 *Equivalent methods and processes* is amended in the first sentence of paragraph (a) by removing the word "amendment" and adding in its place the word "supplement".

§ 610.11 [Amended]

5. Section 610.11 *General safety* is amended in the third sentence of the introductory text by removing the words "an amendment" and adding in their place the words "a supplement".

§ 610.53 [Amended]

6. Section 610.53 *Dating periods for licensed biological products* is amended in paragraph (d) by removing the words "an amendment" and by adding in their place the words "a supplement".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

7. The authority citation for 21 CFR part 630 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 (42 U.S.C. 216, 262, 263, 263a, 264).

§ 630.10 [Amended]

8. Section 630.10 *Poliovirus Vaccine Live Oral Trivalent* is amended in paragraph (c)(3) by removing the word "amendment" and by adding in its place the word "supplement".

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

9. The authority citation for 21 CFR part 640 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 (42 U.S.C. 216, 262, 263, 263a, 264).

§ 640.6 [Amended]

10. Section 640.6 *Modifications of Whole Blood* is amended in the introductory text by removing the words "an amendment" and adding in their place the words "a supplement".

§ 640.21 [Amended]

11. Section 640.21 *Suitability of donors* is amended in paragraph (c) by removing the words "an amendment" and adding in their place the words "a supplement".

§ 640.22 [Amended]

12. Section 640.22 *Collection of source material* is amended in paragraph (c) by removing the words "an amendment" and adding in their place the words "a supplement".

§ 640.64 [Amended]

13. Section 640.64 *Collection of blood for Source Plasma* is amended in the second sentence of paragraph (c) by removing the words "an amendment" and adding in their place the words "a supplement".

§ 640.74 [Amended]

14. Section 640.74 *Modification of Source Plasma* is amended in paragraph (a) by removing the words "an amendment" and by adding in their place the words "a supplement".

Dated: September 15, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–23899 Filed 9–27–94; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300362; FRL–4912–5]

RIN 2070–AB78

Neomycin Phosphotransferase II; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of neomycin phosphotransferase II (NPTII) and the genetic material necessary for its production when used as a plant pesticide inert ingredient. Monsanto Co. petitioned EPA for this exemption.

EFFECTIVE DATE: This regulation becomes effective September 28, 1994.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300362], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (tolerance fees), P.O. Box 36027M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Phillip O. Hutton, Product Manager (PM 18), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC. Office location and telephone number: Rm. 213, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 8, 1993 (58 FR 64582, 64583), EPA issued notices which announced that Monsanto Co., 700 Chesterfield Parkway North, St. Louis, MO 63193, had submitted a pesticide petition (PP 3F4273) to EPA proposing to amend 40 CFR part 180 to establish an exemption

from the requirement of a tolerance for neomycin phosphotransferase II (NPTII), and the genetic material necessary to produce NPTII when produced in plants as a plant pesticide inert ingredient. The Agency did not receive any comments on the notices. Selectable markers such as NPTII are considered inert ingredients by the Agency when they are introduced into a plant in order to ensure or confirm the presence of a plant pesticide. The genetic material necessary to produce NPTII (the NPTII gene) is also considered part of the inert ingredient; therefore, the NPTII gene is also addressed in this final rule.

Neomycin phosphotransferase II (NPTII) is uniquely different from other types of inert ingredients because it is a selectable marker used to identify plant cells early in the product development that had been successfully transformed to express the active ingredient.

The data submitted in the petition and other relevant material have been evaluated and deemed sufficient to support the tolerance. The rationale for this decision is described below.

Assessment of Data

The Agency has evaluated the toxicology data, information on product identity, equivalence of microbially and plant produced NPTII, and other information provided by the petitioner. The information showed that the plant and microbially produced protein are similar with respect to the protein characteristics of amino acid sequence, enzyme activity, electrophoretic mobility, lack of glycosylation, and specific antibody recognition. These findings justified the use of microbial protein in the toxicity studies. The registrant provided the following studies: Acute Oral Toxicity of NPTII in Mice and an In Vitro Digestion of the NPTII Protein. A single oral exposure dose of 5 g/kg NPTII protein produced no adverse effects in mice. The In Vitro Digestion study showed that the protein was rapidly degraded in simulated gastric or intestinal digestive fluids to fragments that were no longer recognized by specific antibodies to NPTII. These results suggest the NPTII protein will not survive passage through the gastrointestinal tract. Therefore, the Agency concluded that the information provided was sufficient to assess the acute toxicity of NPTII when used as a marker gene in transgenic plants expressing plant pesticides and to justify an exemption from the requirement for a food tolerance for residues of the inert. The Agency recognizes that alternative information could be used to indicate the lack of mammalian toxicity and to justify a tolerance exemption.

Since no toxicity was indicated, residue chemistry data were not required. Residue data are necessary only if the submitted toxicity studies indicate that additional toxicology data were needed. These additional data were not needed. Therefore, no residue data are required in order to grant an exemption from the requirement of a tolerance for the plant pesticide inert ingredient neomycin phosphotransferase II when used as a plant pesticide inert ingredient, as expressed in plant cells.

The exemption from a tolerance for the genetic material which encodes for production of NPTII is based on the fact that the nucleic acids which form the genetic material are found in all foods and have not, by themselves, been associated with toxic or pathogenic effects in animals and humans. None of the constituents of nucleic acids are known to be acute toxicants by themselves but, like proteins and other normal constituents in food, may cause indirect, adverse metabolic effects if consumed exclusively at high doses over a long period of time in the absence of a normal diet. The NPTII gene will not occur at these high amounts in plants. Thus, EPA does not believe there is a potential for adverse health effects related to the consumption of plants containing the NPTII gene.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition because the data/information submitted demonstrate that this plant-pesticide inert ingredient (NPTII) and the NPTII gene are not toxic to mammalian species. No enforcement actions are expected based upon the level of residue for NPTII and the genetic material necessary for its production. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption.

Based on the above information and review of its use, EPA has found that when used in accordance with good agricultural practice, this ingredient is useful for the purpose for which the tolerance exemption is sought. Based on the information considered, EPA concludes that a tolerance is not necessary to protect the public health. Therefore, the exemption from the requirement of a tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/or a request for a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 2 of Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic effect on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (49 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 1994.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1134, to read as follows:

§ 180.1134 Neomycin phosphotransferase II and genetic material necessary for its production; exemption from the requirement of a tolerance.

The neomycin phosphotransferase II (NPTII) and the genetic material necessary for the production of this protein are exempted from the requirement of a tolerance in or on all raw agricultural commodities when used as a plant-pesticide inert ingredient.

[FR Doc. 94–23762 Filed 9–27–94; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7603]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., Room 417, Washington, DC 20472, (202) 646–3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 et seq., unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Deputy Associate Director finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Deputy Associate Director has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR,