CIV: Yes, for 4A003.d (having a 3–D vector rate less than 10 M vectors/sec), .e, .f and .g.

* * * * *

4D001 ''Software'' specially designed or modified for the ''development'', ''production'' or ''use'' of equipment controlled by 4A001 to 4A004, 4A101, or ''software'' controlled by 4D001 to 4D003.

License Requirements

Reason for Control: NS, MT, CC, AT, NP, XP.

Control(s)	Country chart
NS applies to ''software'' for equipment controlled by 4A001 to 4A004, 4D001 to 4D003.	NS Column 1.
MT applies to ''software'' for equipment controlled by 4A001 to 4A003 or 4A101 for MT reasons.	MT Column 1.
CC applies to ''software'' for equipment controlled by 4A003 for CC reasons.	CC Column 1.
AT applies to entire entry	AT Column 1.

NP applies to ''software'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.3(b) of the EAR for information on applicable licensing review policies.

XP applies to ''software'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.12 of the EAR for information on applicable licensing review policies.

* * * * *

4D002 ''Software'' specially designed or modified to support ''technology'' controlled by 4E001 or 4E002.

License Requirements

Reason for Control: NS, MT, AT, NP, XP.

Control(s)	Country chart
NS applies to entire entry	NS Column 1.
MT applies to ''software'' for equipment controlled by 4A001 to 4A003 or 4A101 for MT reasons.	MT Column 1.
AT applies to entire entry	AT Column 1.

NP applies to ''software'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.3(b) of the EAR for information on applicable licensing review policies.

XP applies to ''software'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.12 of the EAR for information on applicable licensing review policies.

* * * * *

4E001 ''Technology'' according to the General Technology Note, for the ''development'', ''production'' or ''use'' of equipment controlled by 4A001 to 4A004, 4A101 or ''software'' controlled by 4D001 to 4D003.

License Requirements

Reason for Control: NS, MT, CC, AT, NP, XP.

Control(s)	Country chart
NS applies to ''technology'' for equipment controlled by 4A001 to 4A004, 4D001 to 4D003.	NS Column 1.
MT applies to ''technology'' for equipment controlled by 4A001 to 4A003, 4A101 4D001 or 4D002 for MT reasons.	MT Column 1.
CC applies to ''technology'' for equipment controlled by 4A003 for CC reasons.	CC Column 1.
AT applies to entire entry	AT Column 1.

NP applies to ''technology'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.3(b) of the EAR for information on applicable licensing review policies.

XP applies to ''technology'' for computers with a CTP greater than 2,000 Mtops, unless a License Exception is available. See § 742.12 of the EAR for information on applicable licensing review policies.

* * * * *

Dated: December 18, 1996.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 96–32483 Filed 12–20–96; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 93N–0153]

RIN 0910–AA19

Food Labeling; Nutrient Content Claims and Health Claims; Restaurant Foods; 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 2, 1996 (61 FR 40320). The document amended the food labeling regulations to remove the provisions that exempt restaurant menus from the requirements for how nutrient content claims and health claims are to be made and from the requirements for the provision of nutrition information with respect to the nutrients that are the basis for the claim, when claims are made. The document was published with some errors. Among other things, FDA inadvertently neglected to remove the reference to restaurant menus from 21 CFR 101.13(b). This document corrects those errors.

EFFECTIVE DATE: May 2, 1997.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

These corrections do not, in any way, alter the scope or intent of the August 2, 1996, final rule.

In FR Doc. No. 96–19645, appearing on page 40320 in the Federal Register of Friday, August 2, 1996, the following corrections are made:

1. On page 40321, in the first column, in the second full paragraph, in the third and fourth lines, ''§ 101.13(q)(5) (21 CFR 101.13(q)(5)) exempts'' is corrected to read ''§ 101.13(b) and (q)(5) (21 CFR 101.13(b) and (q)(5)) exempt''.

2. On page 40325, in the third column, in the first full paragraph, in line 12, after ''(2)'' the phrase ''from § 101.13(b), pertaining to nutrient content claims, the language that reads ''* * *, with the exception to such claims on restaurant menus, * * *'';'' is added, and in line 13 add ''(3)'' before the phrase ''from § 101.13(q)(5),''; and in line 16, ''(3)'' is removed and ''(4)'' is added in its place.

3. On page 40328, in the second column, in the 18th line from the bottom of the page, ''(b) and '' is added between ''101.13'' and ''(q)(5)''. In the third column, in the second full paragraph, the first sentence is corrected to read ''Thus, the deletion of the phrase '(except for menus)' that exempted menus from nutrient content claim requirements in §§ 101.10 and 101.13(q)(5) and the deletion of the phrase ',with the exception of such claims on restaurant menus,' in § 101.13(b) will be effective on May 2, 1997.''

4. On page 40331, in the first column, under the caption ''*Description*:'', in line 10, ''(b) and '' is added between ''101.13'' and ''(q)(5)''. On the same page, in the second column, in the first full paragraph, in line 25, ''(b) and '' is added between ''101.13'' and ''(q)(5)'', and in the same paragraph, the first 23 lines are removed. The paragraph now begins with ''Once it becomes effective''.

5. On page 40332, in the second column, amendatory item ''3.'' is corrected to read as follows:

3. Section 101.13 is amended by revising the introductory text of paragraphs (b) and (q)(5) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) A claim that expressly or implicitly characterizes the level of a nutrient (a nutrient content claim) of the type required in nutrition labeling under § 101.9 may not be made on the label or in labeling of foods unless the claim is made in accordance with this section and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

* * * * *

(q) * * *

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

* * * * *

Dated: December 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32428 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Bolus

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merck Research Laboratories. The NADA provides for use of an ivermectin-containing, sustained-release bolus in cattle for treatment and control for approximately 135 days of certain internal and external parasitic infections throughout the grazing season.

EFFECTIVE DATE: December 23, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065–0914, filed NADA 140–988, which provides for the use of Ivomec® (1.72 grams ivermectin) Sustained-Release Bolus for Cattle for the treatment and control of certain gastrointestinal roundworm, lungworm, mange mite, sucking lice, cattle grub, and tick infections in cattle weighing at least 275 pounds (lb) (125 kilograms (kg)) but not more than 660 lb (300 kg) of body weight on the day of administration. The NADA is approved as of November 18, 1996, and the regulations are amended in 21 CFR part 520 by adding new § 520.1197 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning November 18, 1996, because the application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.1197 is added to read as follows:

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 135 days), of gastrointestinal roundworms *Haemonchus placei, Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei, T. colubriformis, Cooperia* spp., *Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum;* lungworms *Dictyocaulus viviparus;* grubs *Hypoderma* spp.; sucking lice *Linognathus vituli, Solenopotes capillatus;* mange mites *Psoroptes ovis, Sarcoptes scabiei,* and ticks *Amblyomma americanum.*

(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.