Research (HFD–605), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION:

I. Background

The 1984 amendments included a provision, codified under section 505(j)(4)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(4)(B)(iv)), granting 180 days of marketing exclusivity to the first applicant to submit an ANDA containing a challenge to a listed patent. Regulations interpreting this provision were proposed in 1989 (54 FR 28872, July 10, 1989), and made final in 1994 (59 FR 50338, October 3, 1994). These regulations are codified under § 314.107(c) (21 CFR 314.107(c)).

The regulations state that for a generic drug to qualify for 180 days of marketing exclusivity, the first ANDA applicant submitting a certification under section 505(j)(2)(A)(vii)(IV) of the act (paragraph IV certification) to the listed patent must, in addition to submitting the certification, be sued for patent infringement and successfully defend that suit (§ 314.107(c)). This interpretation has been the subject of legal action in *Inwood Laboratories, Inc.* v. *Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 Fed.3d 712 (D.C.Cir. 1989); *Mova Pharmaceutical Corp.* v. *Shalala*, 955 F. Supp. 128 (D.D.C. 1997), and *Granutec, Inc. et al.* v. *Shalala et al.*, No. 5:97–CV–485–BO(1)(E.D.N.C. July 3, 1997). Both the *Inwood* and *Mova* courts held that 180 days of marketing exclusivity should be granted to the first ANDA applicant who files a paragraph IV certification, regardless of whether the applicant is subsequently sued for patent infringement. The *Mova* decision has been appealed to the U.S. Court of Appeals for the District of Columbia Circuit.

Following the *Mova* decision, in June 1997, the Office of Generic Drugs notified applicants with ANDA's for ranitidine hydrochloride (HCl) that the agency would acquiesce to the court's holding in *Mova*, pending an appellate decision. The agency determined that temporarily acquiescing to the court's holding in *Mova* would promote administrative uniformity in the application of section 505(j)(4)(B)(iv) of the act and would prevent forum shopping among disappointed ANDA applicants. Subsequently, the U.S. District Court for the Eastern District of North Carolina addressed the validity of § 314.107(c) in *Granutec* v. *Shalala*, and, in a holding contrary to the earlier *Mova* decision, ordered FDA to follow its regulations in approving ANDA's for ranitidine HCl. The *Granutec* decision was stayed and is on expedited appeal to the U.S. Court of Appeals for the 4th Circuit.

Because the uncertain state of the law makes it difficult for the industry to make business plans and other arrangements, CDER wishes to clarify its policy with respect to these exclusivity issues, pending their final resolution by the courts.

II. 180-Day Marketing Exclusivity

It is the agency's position that, given the uncertainty created by the conflict among the courts, the most reasonable policy is to apply the 180-day exclusivity provisions of the statute as set forth in § 314.107(c) to all ANDA's to which the regulation would, on its face, apply, whether they were submitted before or after the *Mova* decision. The only ANDA's to which the agency applied the *Mova* analysis, other than those ANDA's directly involved in the *Mova* litigation, were those for ranitidine HCl.

The regulations in § 314.107(c) were issued through notice and comment rulemaking with the active participation of the pharmaceutical industry and consumer groups. They are the product of careful consideration by the agency of the complex factors at issue in granting a period of exclusivity to generic drug applicants and in ensuring that the statute is implemented in a manner most consistent with its original purpose. These regulations will be applied until such time as the appellate courts complete their analyses of the agency's interpretation.

III. Approval of ANDA's After Judgment in the District Courts

The agency does not intend to acquiesce to the court's decision in *Torpharm* v. *Shalala*, Civil Action No. 97–1925 (JR) (D.D.C. Sept. 15, 1997), in which the court, finding that the term ''the court'' in section 505(j)(4)(B)(iii) of the act means district court, ordered FDA to approve an ANDA after the applicant had prevailed in patent infringement litigation in the district court, but before either the appeal was resolved or the 30-month stay had lapsed. The U.S. Court of Appeals for the District of Columbia has granted the appeal of *Torpharm* an expedited review. While *Torpharm* is pending on appeal, FDA will continue to interpret the statute as described in § 314.107(e), which defines ''the court'' as ''the court that enters final judgment from which no appeal can be or has been taken.''

Dated: November 7, 1997.

Roger Williams,

Deputy Center Director for Pharmaceutical Science.

[FR Doc. 97–31150 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 47 new animal drug applications (NADA's) from Rhone Merieux, Inc., and 54 NADA's from Merck Research Laboratories, Division of Merck & Co., Inc., to Merial Ltd.

EFFECTIVE DATE: November 28, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210, and Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065 has informed FDA that it has transferred ownership of, and all rights and interests in, the approved NADA's to Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077.

Accordingly, the agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, and 558 to reflect the change of sponsor. The agency is also amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for Rhone Merieux, Inc., and Merck Research Laboratories, Division of Merck & Co., Inc., because the firm no longer is the holder of any approved NADA's. The drug labeler code assigned to Rhone Merieux, Inc., is being retained as the drug labeler code for Merial Ltd.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 558

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 parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for ''Rhone Merieux, Inc.'' and ''Merck Research Laboratories, Division of Merck & Co., Inc.'' and by alphabetically adding a new entry for ''Merial Ltd.,'' and in the table in paragraph (c)(2) by removing the entry for ''000006'' and by revising the entry for ''050604'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077	050604
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
050604	Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077
* * *	* * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

§ 520.100a [Amended]

4. Section 520.100a *Amprolium drinking water* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.100b [Amended]

5. Section 520.100b *Amprolium drench* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.100c [Amended]

6. Section 520.100c *Amprolium crumbles* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.300a [Amended]

7. Section 520.300a *Cambendazole suspension* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.300b [Amended]

8. Section 520.300b *Cambendazole pellets* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.300c [Amended]

9. Section 520.300c *Cambendazole paste* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.420 [Amended]

10. Section 520.420 *Chlorothiazide tablets and boluses* is amended in paragraph (a)(2) by removing ''000006'' and adding in its place ''050604''.

§ 520.462 [Amended]

11. Section 520.462 *Clorsulon drench* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.804 [Amended]

12. Section 520.804 *Enalapril tablets* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1192 [Amended]

13. Section 520.1192 *Ivermectin paste* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1193 [Amended]

14. Section 520.1193 *Ivermectin tablets and chewables* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1194 [Amended]

15. Section 520.1194 *Ivermectin drench* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1195 [Amended]

16. Section 520.1195 *Ivermectin liquid* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1196 [Amended]

17. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.1197 [Amended]

18. Section 520.1197 *Ivermectin sustained-release bolus* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.2170 [Amended]

19. Section 520.2170 *Sulfabromomethazine sodium boluses* is

amended in paragraph (c) by removing ''000006'' and adding in its place ''050604''.

§ 520.2380a [Amended]

20. Section 520.2380a *Thiabendazole top dressing and mineral protein feed block* is amended in paragraph (c)(2) by removing ''000006'' and adding in its place ''050604''.

§ 520.2380b [Amended]

21. Section 520.2380b *Thiabendazole drench or oral paste* is amended in paragraph (c) by removing ''000006'' and adding in its place ''050604''.

§ 520.2380c [Amended]

22. Section 520.2380c *Thiabendazole bolus* is amended in paragraph (c) by removing ''000006'' and adding in its place ''050604''.

§ 520.2380d [Amended]

23. Section 520.2380d *Thiabendazole, piperazine citrate suspension* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 520.2380f [Amended]

24. Section 520.2380f *Thiabendazole, piperazine phosphate powder* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

25. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1150 [Amended]

26. Section 522.1150 *Hydrochlorothiazide injection* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 522.1192 [Amended]

27. Section 522.1192 *Ivermectin injection* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 522.1193 [Amended]

28. Section 522.1193 *Ivermectin and clorsulon injection* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 522.1452 [Amended]

29. Section 522.1452 *Nalorphine hydrochloride injection* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 522.1885 [Amended]

30. Section 522.1885 *Prednisolone tertiary butylacetate suspension* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

31. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1193 [Amended]

32. Section 524.1193 *Ivermectin pour-on* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 524.1484g [Amended]

33. Section 524.1484g *Neomycin sulfate-thiabendazole-dexamethasone solution* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

§ 524.1883 [Amended]

34. Section 524.1883 *Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment* is amended in paragraph (b) by removing ''000006'' and adding in its place ''050604''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

35. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

36. Section 558.55 *Amprolium* is amended in paragraph (a) by removing ''000006'' and adding in its place ''050604''.

§ 558.58 [Amended]

37. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1), in the ''Limitations'' column by removing ''000006'' each time it appears and adding in its place ''050604''.

§ 558.95 [Amended]

38. Section 558.95 *Bambermycins* is amended in paragraphs (d)(1)(ii)(*b*), (d)(1)(iii)(*b*), (d)(1)(iv)(*b*), (d)(1)(v)(*b*), and (d)(1)(xiii)(*b*)(2)(iii)(*b*) by removing ''000006'' and adding in its place ''050604''.

§ 558.235 [Amended]

39. Section 558.235 *Efrotomycin* is amended in paragraph (a) by removing ''000006'' and adding in its place ''050604''.

§ 558.300 [Amended]

40. Section 558.300 *Ivermectin* is amended in paragraphs (a)(1) and (a)(2) by removing ''000006'' and adding in its place ''050604''.

§ 558.615 [Amended]

41. Section 558.615 *Thiabendazole* is amended in paragraph (a) by removing ''000006'' and adding in its place ''050604''.

Dated: November 10, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–31148 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 96N–0249]

RIN 0910–AB19

Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is granting exemptions from Federal preemption for certain cigarette and smokeless tobacco requirements in Alabama, Alaska, and Utah. These exemptions will permit those States to continue to enforce certain restrictions on the sale and distribution of cigarettes and smokeless tobacco that are more stringent than FDA counterpart restrictions under its regulations.

EFFECTIVE DATE: December 29, 1997.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5321.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)), any State or local requirement applicable to a device is preempted if such requirement: (1) Is different from, or in addition to, any requirement applicable under the act to the device; and (2) relates to the safety or effectiveness of the device or any