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

other matter included in a requirement applicable to the device under the act.

In implementing section 521 of the act, FDA historically has interpreted that provision narrowly and has found it to have preemptive effect only for those State and local requirements that, in fact, clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements (see § 808.1(d) (21 CFR 808.1(d)). In addition, section 521 of the act ''does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act'' (§ 808.1(d)(2)).

Section 521(b) of the act and its implementing regulations provide that by regulation issued after notice and an opportunity for an oral hearing, FDA may exempt a State or local requirement from preemption under such conditions as the agency may prescribe if the requirement is: (1) More stringent than a requirement under the act that would be applicable to the device if an exemption were not in effect; or (2) required by compelling local conditions and compliance with the State or local requirement would not cause the device to be in violation of any requirement applicable under the act.

In the **Federal Register** of November 7, 1996 (61 FR 57685), FDA invited all State and local governments to submit applications for exemptions from preemption for those State and local requirements pertaining to cigarettes and smokeless tobacco that are preempted by the agency's final rule at part 897 (21 CFR part 897) restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents, and that meet the exemption criteria. In order to facilitate and expedite review, FDA stated that it would consider applications in two groups. Group 1 applications are those seeking exemptions from Federal preemption of State and local age and identification requirements. Group 2 applications are those seeking exemptions from Federal preemption of State and local access, labeling, and advertising requirements.

This final rule responds to Group 1 applications for exemptions from preemption for State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco that are different from, or in addition to, FDA requirements under § 897.14(a) and (b). Section 897.14(a) prohibits the sale of cigarettes or smokeless tobacco to any person under age 18. Section 897.14(b) requires that retailers verify, by means of photographic identification containing the bearer's birth date, that the person purchasing the product is at least 18 years of age. No such verification is required for persons over the age of 26.

The November 1996, **Federal Register** notice stated that Group 1 applications should be submitted by December 9, 1996, and that Group 2 applications, for exemption from preemption from any of the requirements under part 897 other than § 897.14(a) and (b), should be submitted by May 6, 1997 (61 FR 57685 at 57686).

In the **Federal Register** of February 19, 1997 (62 FR 7390), FDA issued a proposed rule responding to Group 1 applications submitted by the States of Alabama, Alaska, Utah, and Washington. The proposal gave the public 30 days to submit written comments. The comment period later was reopened for an additional 2 weeks (see 61 FR 11349, March 20, 1996).

FDA proposed to grant exemptions from Federal preemption for requirements in the States of Alabama, Alaska, and Utah. Washington State requirements were not preempted and, therefore, no exemption needed to be granted. The Alabama Code, the Alaska Statutes, and the Utah Code Annotated prohibit the sale of cigarettes or smokeless tobacco to any person under the age of 19. The proposed rule explained that these requirements are different from the age restriction contained in the tobacco rule at § 897.14(a), which prohibits sales of cigarettes or smokeless tobacco to anyone under age 18. However, the proposal stated FDA's tentative conclusion that the higher minimum age for sale of these products will provide increased health benefits and will not impose significant burdens on retailers. Therefore, to the extent that these State requirements are preempted, FDA proposed to grant them exemptions from preemption.

II. Request for a Hearing

FDA received one request for a hearing. Section 521(b) of the act requires that FDA offer an opportunity for an oral hearing to present evidence that the agency should consider before granting or denying exemptions from preemption. The request for a hearing submitted under this rulemaking raised only legal and policy issues that may be addressed adequately without holding an oral hearing. Consequently, consistent with FDA's regulation at 21 CFR 12.24(b), FDA is denying the request. The legal and policy issues raised in the request for a hearing are addressed in section III of this document.

III. Discussion of Comments

FDA received no comments about the agency's action concerning the application submitted by the State of Washington for exemption from Federal preemption for: (1) Section 26.28.080 of the Revised Code of Washington (RCW)[1], a State law prohibiting any person from selling or giving tobacco products to persons younger than 18 years of age, and (2) section 314–10–050 of the Washington Administrative Code (WAC)[2], a State regulation requiring that purchasers of tobacco products provide proof of age by providing certain Government-issued forms of identification. As discussed in the proposal (62 FR 7390 at 7393), FDA determined that portions of the State of Washington statute and regulations are narrower in scope than the tobacco rule and therefore are not preempted. Because neither RCW 26.28.080 nor WAC 314–10–050 prohibits the distribution of free samples of cigarettes and smokeless tobacco to persons 18 years or older, these provisions are less stringent than the total prohibition against free samples in the tobacco rule at § 897.16(d). In addition, to the extent that the RCW 26.28.080 and WAC 314–10–050 apply to products other than cigarettes and smokeless tobacco, they are not preempted by the tobacco rule because the tobacco rule does not establish ''specific counterpart

[1] RCW 26.28.080 Selling or giving tobacco to minor—Belief of representative capacity, no defense—Penalty.

Every person who sells or gives, or permits to be sold or given to any person under the age of eighteen years any cigar, cigarette, cigarette paper or wrapper, or tobacco in any form is guilty of a gross misdemeanor.

It shall be no defense to a prosecution for a violation of this section that the person acted, or was believed by the defendant to act, as agent or representative of another.

[2] WAC 314-10-050 Sales to persons under 18 years of age.

(1) No person may sell or give or in any way provide tobacco products to any person under 18 years of age.

(2) Any person attempting to purchase tobacco products must present identification to show he/she is at least 18 years of age upon the request of any tobacco licensee, employee of tobacco licensee or enforcement officer as defined by RCW 7.8.040.

(3) All identification used to prove age must be officially issued and contain the bearer's age, signature and photograph. The only forms of identification which are acceptable as proof of age for the purchase of tobacco products are:

(a) A liquor control authority card of identification issued by a state of the United States or province of Canada,

(b) A driver's license, instruction permit or identification card issued by a state of the United States or a province of Canada,

(c) A United States military identification card,

(d) A passport, or

(e) A merchant marine identification card issued by the United States Coast Guard.

regulations'' or other requirements with respect to products other than cigarettes or smokeless tobacco (see § 808.1(d)). Finally, WAC 314–10–050 requires purchasers to present identification establishing the purchaser's age and specifies requirements for the type of identification that the purchaser must present. Because FDA has not established any specific counterpart regulations that place an affirmative duty on the purchaser to present identification or that require a specific type of photographic identification containing the bearer's birth date, WAC 314–10–050 is not preempted. Therefore, because RCW 26.28.080 and WAC 314–10–050 are not preempted, no exemption is necessary.

FDA received 15 comments on the proposed rule. Notably, none of the comments argued that FDA should deny the applications for exemption from preemption submitted by Alabama, Alaska, or Utah. In fact, several comments specifically urged that FDA grant these applications because active enforcement of the higher minimum age for sale in the three States has resulted in a decline in illegal sales of tobacco products to underage youths.

The remaining comments, while supporting FDA's proposal to grant exemptions from preemption for the Alabama, Alaska, and Utah requirements, argued that FDA misinterpreted the scope of preemption under 521(a) of the act by failing to find that all State and local requirements that are *less* stringent than Federal counterpart requirements are preempted. These comments urged FDA to reconsider its analysis of the Supreme Court decision in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), in light of *Papike* v. *Tambrands*, 107 F.3d 737 (1997), and argued that the agency's interpretation of the narrow scope of preemption under section 521(a) of the act would undermine State and local efforts to promote public health. A few comments stated that *more* stringent State or local restrictions should not be preempted because they safeguard the public health more than Federal counterpart restrictions do. Several comments argued that *Medtronic* is not dispositive of the extent to which 521(a) of the act preempts State or local tobacco control laws because the Medtronic Court determined whether 521(a) preempts general common law duties, not whether 521(a) would preempt a specific enactment of State or local law. Comments noted that, because State tobacco statutes are positive enactments of State law, they are precisely the type of requirement that is normally preempted by specific FDA requirements.

Comments relied on the recent Ninth Circuit decision, *Papike*, to support their interpretation of *Medtronic* and the scope of preemption under 521(a) of the act. The *Papike* court held that section 521(a) of the act preempts a State common law cause of action for failure to warn because FDA has established specific counterpart labeling regulations mandating the substantive content of the warning for the particular device and disease at issue in that case. The *Papike* court distinguished the case before it, which involved specific Federal requirements applicable to a specific device, from *Medtronic*, which involved general Federal requirements (good manufacturing practices and labeling requirements). (See *Papike* at 740.) Applying the reasoning in Papike, comments argued that specific Federal tobacco requirements preempt specific, and less stringent, State or local counterpart requirements.

FDA is not persuaded that it erred in its determination that 521(a) of the act preempts more restrictive, but not less restrictive, State or local counterpart requirements. First, FDA believes that the Supreme Court in *Medtronic* has addressed the very issue of whether less restrictive State or local requirements are preempted under section 521(a) of the act. As the agency stated in the proposed rule (62 FR 7390 at 7391), the *Medtronic* Court held that State requirements that are similar to, but narrower than, FDA requirements are not preempted under section 521 of the act. The Court reasoned that, while narrower State restrictions might be ''different from'' their more stringent Federal counterpart restrictions, ''* * * such a difference would surely provide a strange reason for finding a pre-emption of a state rule insofar as it duplicates the federal rule'' (*Medtronic*, 116 S.Ct. at 2255). Accordingly, FDA concludes that section 521(a) of the act does not preempt State or local restrictions to the extent that they are similar to, but narrower or less stringent than, counterpart FDA restrictions.

FDA disagrees with the comments' analysis of and reliance on *Papike*. The agency agrees that a determination of whether a State or Federal requirement is general or specific in nature is essential to any analysis of preemption under section 521(a) of the act. That determination, however, is not dispositive as to whether a particular State or local requirement is preempted. Rather, if there are specific Federal and State requirements applicable to the specific device at issue, the next question is whether the State requirement is different from, or in addition to, the Federal requirement. The Court in *Medtronic* concluded that a State or local requirement that is narrower than, or duplicative of, a counterpart Federal requirement, is not ''different from'' the Federal requirement and, consequently, is not preempted under section 521(a) of the act.

Several comments argued that FDA weakened the standard by which a narrower State or local requirement is found to be preempted. *Medtronic* held that State requirements are not preempted if they parallel Federal requirements or insofar as they duplicate Federal requirements (Id.). In the proposed rule (62 FR 7390 at 7391), FDA paraphrased this holding in stating that State or local requirements that are similar to, but narrower than, counterpart Federal requirements are not preempted. FDA believes that it has not weakened the *Medtronic* standard and that its application of the standard articulated by the Supreme Court in *Medtronic* is required by the Court's interpretation of the scope of preemption under section 521 of the act.

Other comments argued that, as a matter of policy, the finding that less stringent State or local requirements are not preempted weakens FDA's tobacco rule and undermines State and local public health initiatives to reduce tobacco use by children and adolescents.

First, the act clearly requires that a State or local enactment be ''different from,'' or ''in addition to'' a counterpart FDA requirement to be preempted, and FDA regulations enumerate the types of evidence or information that the agency will consider in determining whether to grant an exemption from preemption (see 21 CFR part 808). While the agency is always open to receiving information regarding its decisions, including evidence that a State or local requirement impairs the agency's ability to enforce its regulations, preemption does not occur under section 521 of the act absent a showing that such a requirement is ''different from,'' or ''in addition to,'' a specific counterpart FDA requirement. Second, as a matter of policy, FDA believes that States and localities are able to determine whether, in light of the Supreme Court's interpretation of the scope of Federal preemption under 521(a) of the act, additional or new legislation is warranted. If narrower or less stringent State or local requirements were preempted, as comments suggest, those States and localities would be left with no State or local requirements at all. Therefore, contrary to the concern

expressed by comments, the public health protection in those jurisdictions would be diminished, not enhanced.

A few comments urged that, rather than preempt more stringent State or local requirements, FDA should leave them intact. In that case, exemptions from preemption would not be required. Section 521 of the act clearly states that State or local restrictions that are ''different from'' or ''in addition to'' FDA restrictions are preempted. However, FDA will continue to consider applications for exemptions from preemption for more stringent State or local requirements that provide greater public health protection without imposing significant burdens on interstate commerce.

One comment urged FDA to refrain from issuing general determinations concerning whether a certain type of State or local requirement is preempted. Specifically, the comment disagreed with FDA's using as an example of a narrower restriction in the proposed rule State or local laws that hold retailers to a standard lower than strict liability for selling cigarettes or smokeless tobacco to persons under 18. This comment argued that, while as a general rule *Medtronic* holds that narrower State or local laws are not preempted under section 521(a) of the act, FDA should accept evidence that a specific State or local requirement, although narrower, is nonetheless ''different'' from the FDA requirement and preempted under the act.

FDA believes that it is important to provide States and localities with examples of how to apply the agency's interpretation of the scope of preemption under section 521 of the act, especially because the agency refined its interpretation of *Medtronic*. By providing an example FDA intends to assist States and localities in determining whether they need to apply for an exemption. FDA agrees with the comment that the agency must determine whether a particular requirement is preempted on a case-by-case basis considering, among other factors, the statutory, regulatory or other language, any judicial or administrative interpretations, and any information regarding implementation or enforcement of the requirement. Therefore, FDA remains open to receiving specific information regarding a particular State or local requirement and would consider the information in determining whether the requirement were preempted under section 521(a) of the act.

Several comments suggested that FDA preempt certain types of requirements, including State laws that hold retailers to a standard lower than strict liability for illegally selling tobacco products to minors, and State laws that prohibit using minors to aid in the inspection of tobacco retailers[3]. Comments argued that these types of requirements should be preempted because they frustrate the purpose of the tobacco rule by making it difficult for FDA to enforce the Federal requirements.

First, FDA continues to believe that under *Medtronic* State or local requirements holding retailers liable for knowingly or negligently selling cigarettes or smokeless tobacco to persons under age 18 are not preempted. As explained in the proposal (62 FR 7390 at 7391), State or local statutes that require proving a retailer's negligence or knowledge in an underage sale are similar to counterpart Federal requirements holding retailers strictly liable for illegally selling cigarettes or smokeless tobacco to minors, but they are narrower in scope than the tobacco rule's prohibition of sales to persons under age 18 and therefore are not preempted. Second, because FDA does not have before it a positive enactment to consider, the agency declines to issue an opinion on the preemptive effect of section 521 of the act on the types of requirements that prohibit the use of minors in inspections. Without a specific State or local enactment before the agency, including any legislative, administrative, judicial or enforcement history, the agency cannot determine the effect of either section 521(a) of the act or more general principles of Federal preemption.

Therefore, in response to applications received, FDA is granting exemptions from Federal preemption for certain State requirements in Alabama, Alaska, and Utah relating to cigarettes or smokeless tobacco.

List of Subjects in 21 CFR Part 808

Intergovernmental relations, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 808 is amended as follows:

[3] To ensure that retailers are complying with the tobacco rule and refusing to sell cigarettes or smokeless tobacco to persons under age 18, FDA will conduct compliance checks, wherein an adolescent, accompanied by a State commissioned officer, will attempt to purchase cigarettes or smokeless tobacco.

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

2. Section 808.51 is added to subpart C to read as follows:

§ 808.51 Alabama.

To the extent that the age restriction on the sale, barter, and exchange of cigarettes and smokeless tobacco found in Alabama Code, section 13A–12–3, is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

3. Section 808.52 is added to subpart C to read as follows:

§ 808.52 Alaska.

To the extent that the age restriction on the sale and exchange of cigarettes and smokeless tobacco found in Alaska Statutes, sections 11.76.100(a), is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

4. Section 808.94 is added to subpart C to read as follows:

§ 808.94 Utah.

To the extent that the age restriction on sales of cigarettes and smokeless tobacco found in the Utah Code Annotated, section 76–10–104, is preempted under section 521(a) of the act, the Food and Drug Administration has exempted it from preemption under section 521(b) of the act.

Dated: November 18, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–31213 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 723, 724, 845, and 846

RIN 1029–AB90

Implementation of the Debt Collection Improvement Act of 1996

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: This rule implements the Federal Civil Monetary Penalty Inflation