DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin

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 two supplemental new animal drug applications (NADAs) filed by Pharmacia and Upjohn Co. for clindamycin hydrochloride oral dosage forms. The supplement to the NADA for an oral liquid provides for an expanded dose range for the use of clindamycin hydrochloride in both dogs and cats for the treatment of certain bacterial infections. The supplement to the NADA for oral capsules provides for an expanded dose range in dogs and for use of a 300-milligram (mg) strength capsule.

DATES: This rule is effective August 27, 2002.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplements to NADA 135–940 that provides for use of ANTIROBE (clindamycin hydrochloride) Aquadrops Liquid and to NADA 120–161 for ANTIROBE (clindamycin hydrochloride) Capsules. Supplemental NADA 135–940 provides for an expanded dose range for the use of clindamycin hydrochloride in both dogs and cats for the treatment of certain infections associated with bacteria susceptible to clindamycin hydrochloride. Supplemental NADA 120–161 provides for the same expanded dose range in dogs and for use of a 300-mg strength capsule. The supplemental applications are approved as of May 13, 2002, and the regulations are amended in §§ 520.446 and 520.447 (21 CFR 520.446 and 520.447) to reflect these approvals. The basis of these approvals is discussed in the freedom of information summaries. Sections 520.446 and 520.447 are also being revised to reflect a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject 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: 21 U.S.C. 360b.

2. Section 520.446 is revised to read as follows:

§ 520.446 Clindamycin capsules and tablets.

(a) *Specifications*—(1) Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.

(2) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(3) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 000009 for use of capsules described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i) and (d)(2)(i) of this section.

(2) No. 059130 for use of capsules described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii) and (d)(2)(ii) of this section.

(3) No. 059079 for use of tablets described in paragraph (a)(3) of this section as in paragraphs (d)(1)(ii) and (d)(2)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use in dogs*—(1) *Amount*—(i) Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.

(ii) Wounds, abscesses, and dental infections: 2.5 mg/lb of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 mg/lb of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use*—(i) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius)*, deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(ii) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

3. Section 520.447 is revised to read as follows:

§ 520.447 Clindamycin liquid.

(a) *Specifications.* Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 000009 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), and (d)(2)(ii)(A) of this section.

(2) No. 059130 for use as in paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), (d)(2)(i)(B), and (d)(2)(ii)(B) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) Wounds, abscesses, and dental infections: 2.5 to 15 mg per

pound (/lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.

(B) Wounds, abscesses, and dental infections: 2.5 mg per pound (/lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 mg/lb of body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(B) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(2) Cats—(i) *Amount*—(A) 5.0 to 15.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(B) 5.0 to 10.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus* spp., deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*, and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus* spp., *C. perfringens*, and *B. fragilis*.

(B) Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *S. aureus*, *S. intermedius*, and *Streptococcus* spp. Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *C. perfringens* and *B. fragilis*.

Dated: July 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–21733 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 3

RIN 0790–AG92

Transactions Other Than Contracts, Grants, or Cooperative Agreements for Prototype Projects

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule codifies the conditions for appropriate use and defines a nontraditional Defense contractor consistent with section 803 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001. Representatives of the military departments, Defense agencies and other DoD activities, have agreed on a final rule that amends the interim rule as a result of comments received. Audit policy is still being discussed and will be addressed by a separate rule, as appropriate.

EFFECTIVE DATE: This final rule is effective August 27, 2002.

FOR FURTHER INFORMATION CONTACT: Teresa Brooks, (703) 695–8567.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Section 845 of the National Defense Authorization Act for Fiscal Year 1994, Public Law 103–160, as amended, authorizes the Secretary of a Military Department, the Director of Defense Advanced Research Projects Agency and any other official designated by the Secretary of Defense, to enter into transactions other than contracts, grants or cooperative agreements in certain situations for prototype projects that are directly relevant to weapons or weapon systems proposed to be acquired or developed by the Department of Defense. Such transactions are commonly referred to as ''other transaction'' agreements for prototype projects. To the extent that a particular statute or regulation is limited in its applicability to the use of a procurement contract, it would generally not apply to ''other transactions'' for prototype projects.

Part 3 to 32 CFR was established to codify policy pertaining to prototype ''other transactions'' that have a significant impact on the public and are subject to rulemaking. Additional guidance on prototype ''other transactions'' directed at Government officials can be found on the Defense Procurement web site at: *http://www.osd.dp.mil.*

A proposed rule was published in the **Federal Register** for public comment on November 21, 2001 (66 FR 58422–58425). A notice of public meeting was published in the **Federal Register** on March 4, 2002 (67 FR 9632) and held on March 27, 2002. The proposed rule addressed conditions on use of ''other transactions'' for prototype projects, the nontraditional Defense contractor definition and audit policy. Comments on the proposed rule were received from five respondents and approximately 50 representatives of Government and industry attended the public meeting. The majority of the written comments and discussion at the public meeting focused on the audit policy and will be addressed in a later rule. Only one respondent commented on the conditions of law and none commented on the definition of a nontraditional Defense contractor. The following summarizes the comments regarding the conditions of law and the disposition.

A. Consistency of Terms

One respondent identified the use of undefined terms that are confusing (e.g., ''subordinate element of the party or entities,'' ''awardee'') and recommended expanding upon defined terms such a business unit and segment. The respondent recommended defined terms be consistently used through out the rule or definitions be added for undefined terms.

Response: The DoD agrees. The final rule includes additional definitions and made changes to ensure consistent use throughout the rule.

B. Applicability of Limitations

One respondent(s) questioned whether the statement ''As a matter of policy, these same restrictions apply any time cost sharing may be recognized when using OTA'' was intended to apply to all OTAs, not just OTAs for prototype projects. The respondent recommended it be deleted from this rule and be included in a new rule that applies to all OTA.

Response: The DoD agrees the statement was confusing. The final rule establishes ''Limitations on Cost-Sharing'' as a separate section and clarifies that as a matter of policy, the cost-sharing limitations will also be applied to other OT agreements for prototype projects that provide for non-Federal cost-share.