

4160-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 558

[DOCKET NOS. 77N-0230 AND 77N-0316]

DUPLICATION OF INFORMATION

NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS; PENICILLIN- AND TETRACYCLINE (CHLORTETRACYCLINE AND OXYTETRACYCLINE)-CONTAINING PREMIXES; REOPENING OF COMMENT PERIOD

48 FR 19413

4-29-83

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on the proposed rule to revise the regulations governing subtherapeutic use of antibiotic, nitrofurans, and sulfonamide drugs in animal feeds to permit approval of new animal drug applications (NADA's) and supplements for use of penicillin- and tetracycline (chlortetracycline and oxytetracycline)-containing premixes. FDA is reopening the comment period in response to a request from the Natural Resources Defense Council, Inc.

DATE: Comments by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

83-309

77N-0230

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FOR FURTHER INFORMATION CONTACT:

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Rockville, MD 20857,
301-443-4940.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of February 1, 1983 (48 FR 4490), FDA proposed to amend its regulation concerning approval of subtherapeutic use of penicillin- and tetracycline-containing premixes in animal feeds. The proposal provided for the submission of comments by April 4, 1983.

The Natural Resources Defense Council, Inc. (NRDC), in its letter of February 23, 1983, requested information pursuant to the Freedom of Information Act (FOI Act, 5 U.S.C. 552)--specifically, all documents produced or relied on by FDA in reaching its conclusions that: (1) The proposed rule would not significantly increase risks of human exposure to resistant organisms, and (2) the proposed rule could be supported by equity considerations. The agency has responded with a written discussion of the issues that were the subject of the NRDC letter.

In a second letter dated March 24, 1983, NRDC requested that FDA extend the comment period in order to obtain time to file meaningful comments on the proposal. NRDC claimed that it could not file such comments until after FDA provided it with documents it had requested supporting the proposed rule. FDA concludes that additional time for submitting comments is warranted. The NRDC letter requesting documentation and FDA's responses, dated April 18 and April 19, 1983, are available for public inspection in the Dockets Management Branch.

Accordingly, the period for submission of comments by interested persons is reopened until (insert date 30 days after date of publication in the FEDERAL REGISTER). Interested persons may submit written comments to the Dockets Management Branch (HFA-305) (address above). Respondents should submit two copies (except that individuals may submit single copies) identified with Docket Nos. 77N-0230 and 77N-0316. Received comments may be seen in the Dockets Management Branch from 9 a.m. to 4 p.m., Monday through Friday.

Dated: April 22, 1983.

APR 22 1983

William F. Randolph

William F. Randolph
Acting Associate Commissioner for
Regulatory Affairs

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Marcia Trilayson