(2) If you relinquish your insurable share on any insurable acreage of citrus on or before the acreage reporting date for the crop year, insurance will not be considered to have attached to such acreage for that crop year unless:

(i) A transfer of coverage and right to an indemnity, or a similar form approved by us, is completed by all affected parties; and

(ii) We are notified by you or the transferee in writing of such transfer on or before the acreage reporting date.

If you relinquish your share, no premium or indemnity will be due unless a transfer of coverage is properly executed.

9. Causes of Loss

(a) In accordance with the provisions of section 12 (Causes of Loss) of the Basic Provisions (§ 457.8), insurance is provided only against the following causes of loss that occur during the insurance period:

(1) Adverse weather conditions;

(2) Fire, unless weeds and other forms of undergrowth have not been controlled or pruning debris has not been removed from the grove;

(3) Wildlife;

(4) Earthquake;

(5) Volcanic eruption; or

(6) Failure of irrigation water supply, if caused by an insured peril that occurs during the insurance period.

(b) In addition to the causes of loss excluded in section 12 (Causes of Loss) of the Basic Provisions (§ 457.8), we will not insure against damage or loss of production due to:

(1) Disease or insect infestation, unless adverse weather conditions:

(i) Prevents the proper application of control measures or causes properly applied control measures to be ineffective; or

(ii) Causes disease or insect infestation for which no effective control mechanism is available;

(2) Inability to market the citrus for any reason other than actual physical damage from an insurable cause specified in this section. For example, we will not pay you an indemnity if you are unable to market due to quarantine, boycott, or refusal of any person to accept production.

10. Duties in the Event of Damage or Loss

In addition to the requirements of section 14 (Duties in the Event of Damage or Loss) of the Basic Provisions (§ 457.8), the following will apply:

(a) You must notify us within three 3 days of the date harvest should have started if the crop will not be harvested.

(b) You must notify us at least 15 days before any production from any unit will be marketed directly to consumers. We will conduct an appraisal that will be used to determine your production to count for direct marketed production. If damage occurs after this appraisal, we will conduct an additional appraisal. These appraisals, and any acceptable records provided by you, will be used to determine your production to count. Failure to give timely notice that production will be marketed directly to consumers will result in an appraised amount of production to count that is not less than the production guarantee per acre if such failure results in our inability to make the required appraisal.

(c) If you intend to claim an indemnity on any unit, you must notify us prior to the beginning of harvest so that we may inspect the damaged production. You must not sell or dispose of the damaged crop until after we have given you written consent to do so. If you fail to meet the requirements of this section, all such production will be considered undamaged and included as production to count.

11. Settlement Of Claim

(a) We will determine your loss on a unit basis. In the event you are unable to provide production records:

(1) For any optional unit, we will combine all optional units for which acceptable production records were not provided; or

(2) For any basic unit, we will allocate any commingled production to such units in proportion to our liability on the harvested acreage for each unit.

(b) In the event of loss or damage covered by this policy, we will settle your claim by:

(1) Multiplying the insured acreage for each type by its respective production guarantee;

(2) Multiplying each result in paragraph (1) by the respective price election for each type, or variety within a type;

(3) Totaling the results in paragraph (2);

(4) Multiplying the total production to be counted of each type or variety, if applicable (see section 11(c)), by the respective price election;

(5) Totaling the results of paragraph (4);

(6) Subtracting the total of paragraph (5) from the total in paragraph (3); and

(7) Multiplying the result of paragraph (6) by your share;

(c) The total production to count (in cartons) from all insurable acreage on the unit will include:

(1) All appraised production as follows:

(i) Not less than the production guarantee per acre for acreage:

(A) That is abandoned;

(B) Marketed directly to consumers if you fail to meet the requirements contained in section 10;

(C) Damaged solely by uninsured causes; or

(D) For which you fail to provide production records that are acceptable to us;

(ii) Production lost due to uninsured causes;

(iii) Unharvested production determined to be marketable as fresh packed fruit; and

(iv) Potential production on insured acreage that you intend to abandon or no longer care for, if you and we agree on the appraised amount of production. Upon such agreement, the insurance period for that acreage will end. If you do not agree with our appraisal, we may defer the claim only if you agree to continue to care for the crop. We will then make another appraisal when you notify us of further damage or that harvest is general in the area unless you harvested the crop, in which case we will use the harvested production. If you do not continue to care for the crop, our appraisal made prior to deferring the claim will be used to determine the production to count; and

(2) All harvested production marketed as fresh packed fruit from the insurable acreage.

(3) All disposed or sold damaged citrus that was disposed or sold without an inspection or written consent.

(d) Any production will be considered marketed or marketable as fresh packed fruit unless, due to insurable causes, such production was not marketed or marketable as fresh packed fruit.

(e) Citrus that cannot be marketed due to insurable causes will not be considered production to count.

(f) If we determine that frost protection equipment was not properly utilized or not properly reported, the indemnity for the unit will be reduced by the percentage of premium reduction allowed for frost protection equipment. You must, at our request, provide us records showing the start-stop times by date for each period the frost protection equipment was used.

12. Written Agreement

Designated terms of this policy may be altered by written agreement in accordance with the following:

(a) You must apply in writing for each written agreement no later than the sales closing date, except as provided in section 12(e);

(b) The application for written agreement must contain all terms of the contract between you and us that will be in effect if the written agreement is not approved;

(c) If approved, the written agreement will include all variable terms of the contract, including, but not limited to, crop type or variety, the guarantee, premium rate, and price election;

(d) Each written agreement will only be valid for one year (If the written agreement is not specifically renewed the following year, insurance coverage for subsequent crop years will be in accordance with the printed policy); and

(e) An application for written agreement submitted after the sales closing date may be approved if, after a physical inspection of the acreage, it is determined that no loss has occurred and the crop is insurable in accordance with the policy and written agreement provisions.

Signed in Washington, DC., on June 13, 1996.

Kenneth D. Ackerman,

*Manager, Federal Crop Insurance Corporation.*

[FR Doc. 96–15770 Filed 6–19–96; 8:45 am]

**BILLING CODE 3410–FA–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 500

**[Docket No. 95N–0417]**

## Carcinogenicity Testing of Compounds Used in Food-Producing Animals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revise the regulation that sets forth the requirements for the carcinogenicity testing of compounds used in food-producing animals to allow the agency and sponsors greater flexibility when choosing the types of studies used for testing the carcinogenicity of compounds used in food-producing animals. FDA is proposing to revise the study requirements because FDA recognizes that advances in models used to assess the carcinogenicity of compounds have been made. The specific requirement that a sponsor must conduct oral, chronic, dose-response studies would be deleted under the proposed regulation. Sponsors would have more options for testing the carcinogenicity of compounds used in food-producing animals. This proposal implements the goals stated by the National Performance Review.

**DATES:** Written comments by September 3, 1996.

**ADDRESSES:** Written comments to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Margaret A. Miller, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205.

**SUPPLEMENTARY INFORMATION:** Section 500.80(b) (21 CFR 500.80(b)) sets forth the requirements for the carcinogenicity testing of compounds used in food-producing animals. Specifically, the regulation states, ''The bioassays that a sponsor conducts must be oral, chronic, dose-response studies and must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.''

At the time that this regulation was written, a chronic study was considered to be the standard test for carcinogenicity. However, FDA recognizes that advances in models used to assess carcinogenicity have been made in recent years. For example, scientists now agree that, depending on the compound, a chronic study (as required under current regulations) may not measure the appropriate time point necessary to assess carcinogenicity. Study designs other than chronic may result in a better evaluation of the compound. Thus, FDA is proposing to remove the requirement for oral, chronic, dose-response studies to allow sponsors the option of using other study designs when assessing carcinogenicity of compounds used for food-producing animals.

This proposal is aligned with the goals stated by the National Performance Review. This proposed rule is a result of the President's directive to conduct a comprehensive review of all rules to identify those that are obsolete and burdensome and to delete or revise them. The agency has determined that this rule is in need of revision as described herein.

I. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has determined that this action is categorically excluded under 21 CFR 25.24(a)(8). The procedure for testing the carcinogenicity of compounds used for food-producing animals is being revised. This revision will not cause an increase in the existing level of use or cause a change in the intended uses of the product or its substitutes. Therefore, neither an environmental assessment nor an environmental impact statement is required.

II. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would clarify FDA policy and simplify the process for submitting certain applications, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Paperwork Reduction Act of 1995

The agency has determined that this proposed rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

IV. Federalism

FDA has analyzed this proposal in accordance with the principles and criteria set forth in Executive Order 12612 and has determined that this proposal does not warrant the preparation of a Federalism Assessment.

V. Request for Comments

Interested persons may, on or before September 3, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 500 is amended as follows:

## Part 500—General

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

### § 500.80 [Amended]

2. Section 500.80 *Scope of this subpart* is amended in paragraph (b) by removing the phrase ''must be oral, chronic, dose-response studies and.''

Dated: June 13, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–15725 Filed 6–19–96; 8:45 am]

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