



for the protection of investors, and to maintain fair and orderly markets.

Authority; Effective Date; Amendment.

The Commission hereby amends Form 13F, effective immediately, pursuant to the authority set forth in Sections 3(b), 13(f) and 23 of the Exchange Act [15 U.S.C. 78c(b), 78m(f) and 78w]. The Commission finds that the changes in the form are technical in nature and do no more than clarify existing requirements, so that notice and public procedure are not necessary and the amendments may be made effective immediately [5 U.S.C. 553(b), (d)].

Accordingly, General Instruction D of the form prescribed in Section 249.325 of Title 17 of the Code of Federal Regulations is amended to provide as follows:

§ 249.325 Form 13F, report of institutional investment manager pursuant to Section 13(f) of the Securities Exchange Act of 1934.

\* \* \* \* \*

#### General Instructions

\* \* \* \* \*

D. Pursuant to section 13(f)(3) of the Act [15 U.S.C. 78m(f)(3)], the Commission (1) may prevent or delay public disclosure of information on this form in accordance with section 552 of Title 5 United States Code, the Freedom of Information Act [5 U.S.C. 552], and (2) shall not disclose information on this form identifying securities held by the account of a natural person or an estate or trust (other than a business trust or investment company). Requests for confidential treatment of information on this form should be made in accordance with Rule 24b-2 under the Exchange Act [17 CFR 240.24b-2], except that requests seeking to prevent disclosure of information identifying the securities held by the account of a natural person or an estate or trust (other than a business trust or investment company) need not, in complying with paragraph b(2)(ii) of Rule 24b-2, include an analysis of any applicable exemptions from disclosure under the Commission's rules and regulations adopted under the Freedom of Information Act [17 CFR 200.80].

A manager requesting confidential treatment in accordance with the Freedom of Information Act must provide enough factual support for its request to enable the Commission to make an informed judgment as to the merits of the request. The request should address all pertinent factors, including such of the following as may be relevant:

1. If confidential treatment is requested as to more than one holding of securities, discuss each holding separately unless class or classes of holdings can be identified as to which the nature of the factual circumstances and the legal analysis are substantially the same;

2. If a request for confidential treatment is based upon a claim that the subject information is confidential commercial or financial information:

a. Describe the investment strategy being followed with respect to the relevant securities holdings, including the extent of any program of acquisition and disposition (note that the term "investment strategy," as used in this instruction, also includes activities such as risk arbitrage and block positioning);

b. Explain why public disclosure of the securities holdings would, in fact, be likely to reveal the investment strategy; consider this matter in light of the specific reporting requirements of Form 13F (e.g., securities holdings are reported only quarterly and may be aggregated in many cases);

c. Demonstrate that such revelation of an investment strategy would be premature; indicate whether the manager was engaged in a program of acquisition or disposition of the security both at the end of the quarter and at the time of the filing; address whether the existence of such a program may otherwise be known to the public; and

d. Demonstrate that failure to grant the request for confidential treatment would be likely to cause substantial harm to the manager's competitive position; show what use of competitors could make of the information and how harm to the manager could ensue.

3. If the Commission grants a request for confidential treatment, it may delete details which would identify the manager and use the information in tabulations required by Section 13(f)(3) absent separate showing that such use of information could be harmful.

By the Commission.

Dated: June 28, 1979.

George A. Fitzsimmons,  
Secretary.

[FR Doc. 79-20888 Filed 7-5-79; 8:45 am]

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## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

#### 21 CFR Parts 522 and 558

[Docket No. 76N-0002]

#### Diethylstilbestrol (DES) in Edible Tissues of Cattle and Sheep; Revocations

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revoking the animal drug regulations that provide information about new animal drug applications (NADA's) for the use of DES in cattle and sheep as an additive to animal feed and as a subcutaneous implant. This action is based on the withdrawal of approval of NADA's following an evidentiary hearing.

Elsewhere in this issue of the Federal Register, FDA announces withdrawal of the NADA's.

**DATES:** This action is effective with respect to the manufacture and shipment of DES animal drugs on July 13, 1979; it is effective with respect to the use of DES animal drugs and the manufacture, shipment, and use of feed containing DES on July 20, 1979; it will not be made effective with respect to the edible products of animals treated with DES solely before the effective date for use of DES animal drugs and DES-treated animal feeds.

**FOR FURTHER INFORMATION CONTACT:** Constantine Zervos, Scientific Liaison and Intelligence Staff (HFY-31), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4490.

**SUPPLEMENTARY INFORMATION:** Elsewhere in this issue of the Federal Register, FDA announces the withdrawal, after an evidentiary hearing, of the approval of NADA's 10421, 10964, 11295, 11485, 12553, 15274, 31448, 34916, 44344, 45981, and 45982. These NADA's are for DES implants and liquid and dry feed premixes for use in cattle and sheep.

21 CFR 522.640 and 558.225 provide information concerning the NADA's whose approval has been withdrawn. FDA is at this time revoking those regulations, and their cross-references, pursuant to 21 U.S.C. 360b(i).

§ 522.640 [Revoked]

§ 558.76 [Amended]

§ 558.78 [Amended]

§ 558.225 [Revoked]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 522 by revoking § 522.640 *Diethylstilbestrol*; and in Part 558 by deleting paragraph (e)(3)(v) in § 558.76 *Bacitracin methylene disalicylate*; by deleting paragraph (e)(3)(iv) in § 558.78 *Bacitracin, zinc*; and by revoking § 558.225 *Diethylstilbestrol*.

**EFFECTIVE DATE:** This rule is effective with respect to the manufacture and shipment of DES animal drugs on July 13, 1979; it is effective with respect to the use of DES animal drugs and the manufacture, shipment, and use of feed containing DES on July 20, 1979; it will not be made effective with respect to the

edible products of animals treated with DES solely before the effective date for use of DES animal drugs and DES-treated animal feeds.

(Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b).)

Dated: June 29, 1979.

Donald Kennedy,

Commissioner of Food and Drugs.

[FR Doc. 79-20777 Filed 7-2-79; 11:45 am].

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## 21 CFR Part 556

[Docket No. 76N-0002]

### Tolerances for Residues of New Animal Drugs in Food; Diethylstilbestrol (DES) in Edible Tissues of Cattle and Sheep; Revocation of Test Methods Regulation

AGENCY: Food and Drug Administration.  
ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revoking the animal drug regulation that sets forth the methods of analysis approved for the detection of residues of DES in the edible tissues of cattle and sheep treated with DES.

**DATES:** This action is effective with respect to the manufacture and shipment of DES animal drugs on July 13, 1979; it is effective with respect to the use of DES animal drugs and the manufacture, shipment, and use of feed containing DES on July 20, 1979; it will not be made effective with respect to the edible products of animals treated with DES solely before the effective date for use of DES animal drugs and DES-treated animal feeds.

**FOR FURTHER INFORMATION CONTACT:** Constantine Zervos, Scientific Liaison and Intelligence Staff (HFY-31), Food and Drug Administration, Department of Health, Education, and Welfare, 5800 Fishers Lane, Rockville, MD 20857, 301-443-4490.

**SUPPLEMENTARY INFORMATION:** FDA is revoking 21 CFR 556.190, which identifies the mouse uterine/paper chromatography method as the method of examination prescribed for the quantitative and qualitative identification of DES in the edible products of beef cattle and sheep. New animal drug applications (NADA's) have been approved by FDA for the use of DES in cattle and sheep as a feed additive (see 21 CFR 558.225) and as a subcutaneous implant (see 21 CFR 522.640). By order signed this date, the FDA is withdrawing approval of all NADA's for these products. Notice of

that order, and final rule revoking 21 CFR 522.640 and 558.225, appears elsewhere in this issue of the Federal Register.

The statutory provision for approval (and withdrawal of approval) of NADA's contains a clause (the "Delaney Clause") that prohibits the approval of any animal drug that induces cancer when ingested by man or animal, 21 U.S.C. 360b(d)(1)(H). DES has been shown to be a carcinogen in animals and has been associated with carcinogenesis in humans.

FDA has previously considered the NADA's for DES to be approvable, despite the prohibition of the Delaney Clause, on the basis of a statutory exception to that clause. The exception (21 U.S.C. 360b(d)(1)(H)) states that the Delaney Clause:

shall not apply with respect to [a drug that has been shown to cause cancer] if the [Commissioner] finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) \* \* \* (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the [Commissioner] by regulations, which regulations shall not be subject to subsections (c), (d), and (h) [of this section]), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals; \* \* \*

This provision has become known as the "DES exception" to the Delaney Clause. The regulation being revoked by this order sets forth the "methods of examination prescribed or approved" by the Commissioner of Food and Drugs by regulations for detecting DES residues in the edible products of cattle and sheep.

FDA proposed to revoke § 556.190 by notice in the Federal Register of March 27, 1974 (39 FR 11299). Comments were solicited on that proposal. In the Federal Register of January 12, 1976 (41 FR 1804), FDA responded to the comments received. In the same document, FDA gave notice of opportunity for hearing on a proposal to withdraw approval of the NADA's for DES. That document stated at 41 FR 1806 that:

The Commissioner intends to revoke these methods at the time of final action based upon this notice of opportunity for hearing. \* \* \* If a hearing is held, the currently approved method will be revoked, and any replacement method(s) demonstrated to be adequate will be designated at the time the Commissioner issues a final order based upon the hearing record and the decision of the Administrative Law Judge.

The hearing on the proposed withdrawal of approval of the DES NADA's has been held. The agency's decision based on the hearing record

and on the Administrative Law Judge's initial decision is being issued today.

The agency's decision withdraws approval of the DES NADA's on two independent grounds. First, approval is withdrawn based upon this action revoking the approved analytical method for detecting DES residues. When there is no approved analytical method for a carcinogen, the DES exception does not exempt the drug in question from the Delaney Clause. The Delaney Clause, thus, requires withdrawal of approval of the NADA's involved. Second, the decision concludes, on the basis of new evidence evaluated together with existing evidence, that DES has not been shown to be safe for its intended uses as an animal drug. The agency's decision will be published in the Federal Register in the near future.

The issues whether the approved analytical method (the mouse uterine/paper chromatography method) or any other analytical methods are acceptable for use with DES were addressed in the administrative hearing. As explained in the agency's decision evaluating the record at that hearing, nothing in that record demonstrates that the agency's decision in 1976 to revoke the approved method was incorrect. In addition, no other analytical method was shown to be acceptable for DES.

In summary, the decision's findings are as follows: Insufficient testing has been performed to determine which of the components of DES residues are of toxicological interest and must be measured by an analytical method for DES. The mouse uterine/paper chromatography method does not detect DES residues at a level at which those residues have been shown not to present a significant risk of cancer. In addition, the approved method has not been shown to be adequately specific or practical for regulatory purposes.

The mouse uterine/paper chromatography method, though it has been approved since 1963, is so impractical for regulatory purposes that the Department of Agriculture does not use it in the only ongoing program for surveying animal tissues for DES residues. The gas chromatography/mass spectrometry method, which the Department of Agriculture uses, does not qualify as an acceptable alternative method for DES. No method can be considered acceptable without knowledge about what residues of DES are of toxicological concern and thus must be detected by the method. In any case, the gas chromatography/mass spectrometry method does not detect DES residues at a level at which those