

(HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning April 6, 1995, because the supplemental NADA contains reports of new clinical investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Three years of marketing exclusivity applies only to the use for which the supplemental NADA is approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 522**

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 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2680 is amended by adding new paragraph (d)(3) to read as follows:

**§ 522.2680 Zeranol.**

\* \* \* \* \*

(d) \* \* \*

(3) *Steers*—(i) *Amount.* 72 milligrams (six 12-milligram pellets) per animal.

(ii) *Indications for use.* For increased rate of weight gain in steers fed in confinement for slaughter.

(iii) *Limitations.* Implant subcutaneously in ear only.

Dated: May 5, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-12094 Filed 5-16-95; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-30072L; FRL-4950-7]

**Tolerance Processing Fees**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule increases fees charged for processing tolerance petitions for pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). The change in fees reflects a 3.22 percent increase in locality pay for civilian Federal General Schedule (GS) employees working in the Washington, DC/Baltimore, MD metropolitan area in 1995.

**EFFECTIVE DATE:** June 16, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Concerning this rule contact: By mail: Delores A. Furman, Program Management and Support Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 700-G, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703-305-7016), furman.delores. Concerning tolerance petitions and individual fees contact: Jim Tompkins (703-305-5697)

**SUPPLEMENTARY INFORMATION:** The EPA is charged with administration of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 authorizes the Agency to establish tolerance levels and exemptions from the requirements for tolerances for raw agricultural commodities. Section 408(o) requires that the Agency collect fees as will, in the aggregate, be sufficient to cover, among other things, the costs of processing petitions for pesticide products, i.e., that the tolerance process be as self-supporting as possible. The current fee schedule for tolerance petitions (40 CFR 180.33) was published in the **Federal Register** on June 2, 1994 (59 FR 28482) and became effective on July 5, 1994. At that time the fees were increased 4.23 percent in accordance with a provision in the regulation that provides for automatic annual adjustments to the fees based on annual percentage changes in Federal

salaries. The specific language in the regulation is contained in paragraph (o) of § 180.33 and reads in part as follows:

(o) This fee schedule will be changed annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale.... When automatic adjustments are made based on the GS pay scale, the new fee schedule will be published in the **Federal Register** as a final rule to become effective thirty days or more after publication, as specified in the rule.

The Federal Employees Pay Comparability Act of 1990 (FEPCA) initiated locality-based comparability pay, known as "locality pay." The intent of the legislation is to make Federal pay more responsive to local labor market conditions by adjusting General Schedule salaries on the basis of a comparison with non-Federal rates on a geographic, locality basis.

The processing and review of tolerance petitions is conducted by EPA employees working in the Washington, DC/ Baltimore, MD pay area. The pay raise in 1995 for Federal General Schedule employees working in the Washington, DC/Baltimore, MD metropolitan pay area is 3.22 percent; therefore, the tolerance petition fees are being increased 3.22 percent. All fees have been rounded to the nearest \$25.00.

**List of subjects in 40 CFR Part 180**

Administrative practice and procedures, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 5, 1995.

**Daniel M. Barolo,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I, part 180 is amended as follows:

1. The authority citation for Part 180 continues to read as follows:

**Authority:** 21 U.S.C. 346a and 371.

2. Section 180.33 is amended by revising paragraphs (a), (b), (c), (d), (e), (f), (g), (i), (j)(3), and (m) to read as follows:

**§ 180.33 Fees.**

(a) Each petition or request for the establishment of a new tolerance or a tolerance higher than already established, shall be accompanied by a fee of \$60,425, plus \$1,500 for each raw agricultural commodity more than nine on which the establishment of a tolerance is requested, except as provided in paragraphs (b), (d), and (h) of this section.

(b) Each petition or request for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the

same pesticide chemical, or for the establishment of a tolerance on additional raw agricultural commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a fee of \$13,825 plus \$925 for each raw agricultural commodity on which a tolerance is requested.

(c) Each petition or request for an exemption from the requirement of a tolerance or repeal of an exemption shall be accompanied by a fee of \$11,150.

(d) Each petition or request for a temporary tolerance or a temporary exemption from the requirement of a tolerance shall be accompanied by a fee of \$24,150 except as provided in paragraph (e) of this section. A petition or request to renew or extend such temporary tolerance or temporary exemption shall be accompanied by a fee of \$3,425.

(e) A petition or request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level or a higher numerical level shall be accompanied by a fee of \$12,050 plus \$925 for each raw agricultural commodity on which the temporary tolerance is sought.

(f) Each petition or request for repeal of a tolerance shall be accompanied by a fee of \$7,550. Such fee is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be repealed and a fee is paid as required by paragraph (a) of this section.

(g) If a petition or a request is not accepted for processing because it is technically incomplete, the fee, less \$1,500 for handling and initial review, shall be returned. If a petition is withdrawn by the petitioner after initial processing, but before significant Agency scientific review has begun, the fee, less \$1,500 for handling and initial review, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were being submitted for the first time.

\* \* \* \* \*

(i) Objections under section 408(d)(5) of the Act shall be accompanied by a filing fee of \$3,025.

(j) \* \* \*

(3) An advance deposit shall be made in the amount of \$30,175 to cover the costs of the advisory committee. Further advance deposits of \$30,175 each shall be made upon request of the

Administrator when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

\* \* \* \* \*

(m) The Administrator may waive or refund part or all of any fee imposed by this section if the Administrator determines in his or her sole discretion that such a waiver or refund will promote the public interest or that payment of the fee would work an unreasonable hardship on the person on whom the fee is imposed. A request for waiver or refund of a fee shall be submitted in writing to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division (7505C), Washington, DC 20460. A fee of \$1,500 shall accompany every request for a waiver or refund, except that the fee under this sentence shall not be imposed on any person who has no financial interest in any action requested by such person under paragraphs (a) through (k) of this section. The fee for requesting a waiver or refund shall be refunded if the request is granted.

\* \* \* \* \*

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**40 CFR Parts 180, 185, and 186**

[FAP 4H5683/R2131; FRL-4952-5]

RIN 2070-AB78

**Hexazinone; Pesticide Tolerances and Food/Feed Additive Regulations**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This document amends the current tolerance for residues of the herbicide hexazinone (3-(cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4(1*H*,3*H*)-dione) and its metabolites (calculated as hexazinone) in or on sugarcane at 0.2 part per million (ppm) by revoking the current tolerance and reestablishing the same tolerance with regional registration and tolerance as described in 40 CFR 180.1(n). EPA also establishes food and feed additive regulations for residues of hexazinone and its metabolites in sugarcane molasses at 0.5 ppm. E.I. du Pont de Nemours & Co., Inc., requested these regulations pursuant to the Federal Food, Drug and Cosmetic Act.

**EFFECTIVE DATE:** These regulations become effective May 17, 1995.

**ADDRESSES:** Written objections, identified by the document control number, [PP 4H5683/R2131], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [FAP 4H5683/R2131]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7830; e-mail: miller.joanne@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 22, 1995 (60 FR 15113), EPA issued a proposed rule that gave notice that E.I. du Pont de Nemours & Co., Inc., had petitioned EPA under section 408 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, to amend 40 CFR parts 180, 185, and 186 to establish tolerances with regional registration for combined residues of the herbicide hexazinone (3-