approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

**DATE:** Petitions for administrative review by July 18, 1983.

**ADDRESS:** Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Charles H. Kyper, National Center for Devices and Radiological Health (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

**SUPPLEMENTARY INFORMATION:** On November 16, 1982, Apothecary Products Inc., Burnsville, MN, submitted to FDA a supplemental application for premarket approval of Normaline®-250 mg for all soft (hydrophilic) contact lenses. The application was reviewed by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, an FDA advisory committee, which recommended approval of the application. On May 27, 1983, FDA approved the application by a letter to the sponsor from the Associate Director for Device Evaluation of the Office of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295, 90 Stat. 539-583), salt tablets for preparing solutions for use in heat disinfection of soft (hydrophilic) contact lenses were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), such salt tablets are now regulated as class III devices (premarket approval). As FDA explained in a notice pubished in the Federal Register of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continuation of premarket approval requirements for class III devices formerly regulated as new drugs. Furthermore, FDA requires, as a condition for approval, that sponsors of applications for premarket approval of soft contact lenses and lens care solutions for the above use comply with the records and reports provisions of Subpart D of Part 310 (21 CFR Part 310) until these provisions are replaced by similar requirements under the amendments.

A summary of the safety and effectiveness data on which FDA's approval is based is on file with the Dockets Management Branch (address above), and is available upon request from that office. A copy of all approved final labeling is avaiable for public inspection at the Office of Medical Devices—contact Charles H. Kyper (KFK-402), address above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labeling of Normaline®-250 mg states that the solution prepared from the salt tablets is designed for use in heat disinfection of all soft (hydrophilic) contact lenses. Sponsors of any soft (hydrophilic) contact lenses that have been approved for marketing are advised that whenever FDA publishes a notice in the Federal Register of the agency's approval of a new solution for use with an approved soft contact lens, the sponsor of each lens shall correct its labeling to refer to the new solutions at the next printing or at such other time as FDA prescribes by letter to the sponsor. A sponsor who fails to update the restrictive labeling may violate the misbranding provisions of section 502 of the act (21 U.S.C. 352) as well as the Federal Trade Commission Improvement Act (15 U.S.C. 41-58), as amended by the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act (Pub. L. 93-637). Furthermore, failure to update the restrictive labeling to refer to new salt tablets that may be used with an approved lens may be grounds for withdrawing approval of the application for the lens under section 515(e)(1)(F) of the act (21 U.S.C. 360e(e)(1)(F)).

### Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issues to be reviewed, the forms of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 18, 1983, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 7, 1983.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-15879 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

---

**[Docket Nos. 82P-0387 et al.]**

## Availability of Approved Variance for Sunlamp Products

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces that variances from the performance standard for sunlamp products have been approved by the Acting Director, Office of Radiological Health (formerly the Bureau of Radiological Health) of FDA's National Center for Devices and Radiological Health, for certain specified sunlamps and sunlamp products manufactured or imported by seven organizations. The intended use of the products is to produce ultraviolet radiation for tanning the skin.

**DATES:** The effective dates and termination dates of the variances are listed in the table below.

**ADDRESS:** The application and all correspondence on the various applications have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Norbert P. Heib, Jr., National Center for Devices and Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

**SUPPLEMENTARY INFORMATION:** Under § 1010.4 (21 CFR 1010.4) of the regulations governing establishment of performance standards under section

358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), each of the seven organizations listed in the table below has been granted a variance from certain requirements of the performance standard for sunlamp products (21 CFR 1040.20). Approval has been granted for the listed products to vary as specified from that portion of § 1040.20(c)(2)(ii) (21 CFR 1040.20(c)(2)(ii)) requiring the maximum timer interval for a sunlamp product to be 10 minutes or less or from § 1040.20(f)(2)(ii) that specifies the exact warning statement to be included in the user instructions for an ultraviolet lamp not accompanying a sunlamp product. All other provisions of § 1040.20 remain applicable to the listed sunlamp products and ultraviolet lamps.

Each of the variances for the nominally ultraviolet-A (UVA) sunlamp products permits the listed manufacturer or importer to introduce into commerce sunlamp products that have less than 5 percent of their ultraviolet radiation at wavelengths shorter than 320 nanometers. FDA's experience with this kind of sunlamp product indicates that the relatively lengthy exposure recommended by the manufacturer does not result in severe, acute skin burns or corneal injury. Therefore, some of the requirements of § 1040.20 are not appropriate for these UVA products. Even though the skin hazard is reduced, there is still a need to wear protective eyewear to eliminate the unnecessary risk to chemically sensitized lenses or of cornea damage or of long-term development of lens opacities.

Suitable or alternate means of radiation protection will be provided by constraints on the physical and optical design and by warnings in the user manual and on the products for all of the variances in lieu of the requirements listed in the table that were determined to be inappropriate. Therefore, on the dates specified in the table below, FDA approved the requested variances by letter to each manufacturer or importer from the Acting Director, Office of Radiological Health.

So that the product will bear evidence of the variance approved for the manufacturer of that product, each product shall bear on the certification label required by § 1010.2 (21 CFR 1010.2(a)) the docket number and effective date of the variance as specified in the table below.

| Docket No. | Organization Granted the Variance | Sunlamp product | Paragraph in 21 CFR 1040.20 pertaining to variance | Effective date/termination date |
|---|---|---|---|---|
| 82P-0387 | Voltarc Tubes, Inc., 176 Linwood Avenue, Box 688, Fairfield, CT 06430. | UVA Ultraviolet Lamps Manfactured by Voltarc Tubes, Inc. | (f)(2)(ii) | Feb. 10, 1983, Feb 10, 1988. |
| 83P-0003 | Uvatec, Inc., 8430 Santa Monica Blvd., Suite 200, Los Angeles, CA 90069. | UVA Suntanning Bed and Canopy (Model Suntamed 4000). UVA Tanning Canopy (Model Suntamed 2000). | (c)(2)(ii) | Mar. 25, 1983, Mar. 25, 1988. |
| 83P-0019 | Creative Marketing Concepts, Inc., 25 Sixth Road Woburn, MA 01801. | UVA Suntanning Booth (The Sun Capsule) | (c)(2)(ii) | Feb. 16, 1983, Feb. 16, 1988. |
| 83P-0045 | The Tanning Place, Inc., 2676 Hamburgh Street, Schenectady, NY 12303. | UVA Suntanning Booth | (c)(2)(ii) | Mar. 7, 1983, Mar. 7, 1988. |
| 83P-0046 | Zip Tan, P.O. Box 4840, Mesa, AZ 85201. | UVA Suntanning Booth | (c)(2)(ii) | Mar. 7, 1983, Mar. 7, 1988. |
| 83P-0100 | Unterwasser-Electric GmbH & CO KG, Postfach 2020, 7070 Schwabisch Gmund, Republic of West Germany. | UVA Suntanning Systems Models: UWE-Sun Stream, UWE-Bermuda, UWE-Brozarette, UWE-Super Nova. | (c)(2)(ii) | Apr. 1, 1983, Apr. 1, 1988. |
| 83P-0101 | Eurosun, Inc., 21538 Mountsfield Drive, Golden, CO 80401. | UVA Suntanning Beds, Models: Eurosun 800, Eurosun 2400. | (c)(2)(ii) | Apr. 1, 1983, Apr. 1, 1988. |

In accordance with § 1010.4, the application and all correspondence (including the written notice of approval) on the various applications have been placed on public display in the Dockets Management Branch, Food and Drug Administration (address above), and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 1983.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-15878 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

---

[Docket No. 83M-0138]

## Alcon Laboratories, Inc.; Premarket Approval of Opt-Clean™ Cleaning Solution

*Correction*

In FR Doc. 83-12721, beginning on page 21657, in the issue of Friday, May 13, 1983, make the following corrections:

1. On page 21657, in the third column, in the fifth line from the bottom, "94-925" should read "94-295".

2. On page 21658, in the second column, in the third line from the top, "505" should read "515".

BILLING CODE 1505-01-M

---

[Docket No. 83N-0115; DESI 12368]

## Isoproterenol Hydrochloride for Oral Use; Drugs for Human Use; Drug Efficacy Study Implementation; Revocation of Exemption; Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application

*Correction*

In FR Doc. 83-13410, beginning on page 22801, in the issue of Friday, May 20, 1983, on page 22801, in the third column, in the first complete paragraph, in the fourth line "12-638" should read "12-368"; in the second complete paragraph, the third line from the end "heat" should read "heart"./

BILLING CODE 1505-01-M

---

[Docket No. 82P-0388]

## General Medical Co.; Drionic Iontophoretic Sweat Inhibition Device; Panel Recommendation on Petition for Reclassification

*Correction*

In FR Doc. 83-14544 beginning on page 24981 in the issue of Friday, June 3, 1983, make the following corrections:

1. On page 24981, column two, **SUPPLEMENTARY INFORMATION,** paragraph two, line twelve, "(21 U.S.C. 360 (f)(1))" should read "(21 U.S.C. 360c(f)(1))."

2. On page 24983, column two, paragraph two, line fourteen, "buillae" should read "bullae."

BILLING CODE 1505-01-M

[Docket No. 83N-0154]

## International Drug Scheduling; Convention of Psychotropic Substances; Benzodiazepines

*Correction*

In FR Doc. 83-12844, beginning on page 21661, in the issue of Friday, May 13, 1983, on page 21662, in the first column, in the fourth complete paragraph, in the fourth line, "estaolam" should read "estazolam".

BILLING CODE 1505-01-M

---

[Docket No. 83F-0157]

## Ciba-Geigy Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Vir Anand, Bureau of Foods (HHF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3671) has been filed by Ciba-Geigy Corp., Three Skyline Drive, Hawthorne, NY 10532, proposing that the food additive regulations be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) intended to contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: June 2, 1983.

**Richard J. Ronk,**

*Acting Director for Bureau of Foods.*

[FR Doc. 83-16123 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

---

[Docket No. 83F-0164]

## Calgon Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** Food and Drug Administration (FDA) is announcing that the Calgon Corp. has filed a petition proposing that the food additive regulations be amended to provided for the safe use of 2-(4-thiazolyl)benzimidazole as a component of adhesives and paper and paperboard.

**FOR FURTHER INFORMATION CONTACT:** Geraldine E. Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3627) has been filed by Calgon Corp., Box 1346, Pittsburgh, PA 15230, proposing the § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of 2-(4-thiazolyl)benzimidazole as a component of paper and paperboard for use in food contact applications and that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of this additive as a component of adhesives.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: June 9, 1983.

**Sanford A. Miller,**

*Director, Bureau of Foods.*

[FR Doc. 83-16272 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

---

## Consumer Participation; Open Meetings

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

**Los Angeles District Office**, chaired by Abraham I. Kleks, District Director. The topic to be discussed is: Health Fraud.

Date: Monday June 27, 1983, 2:30 p.m.

Address: Parks and Recreation Bldg., 208 Park Ave., San Fernando, CA 91340.

For further information contact: Irene G. Caro, Consumer Affairs Officer, Food and Drug Administration, 1521 West Pico Blvd., Los Angeles, CA 90015, 213-688-4395.

**Brooklyn District Office**, chaired by George J. Gerstenberg, District Director. The topic to be discussed is: Direct-to-Consumer Advertising of Prescription Drugs.

Date: Wednesday, June 29, 1983, 1:30 p.m.

Address: 26 Federal Plaza, Rm. 305, New York, NY 10278.

For further information contact: Herman B. Janiger, Consumer Affairs Officer, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 212-965-5754.

**Baltimore District Office**, chaired by Thomas L. Hooker, District Director. The topic to be discussed is: Direct-to-Consumer Advertising of Prescription Drugs.

Date: Tuesday, July 19, 1983, 10 a.m. to 12 m.

Address: Rosenstock Hall, Hood College, Frederick, MD 21701.

For further information contact: Anne B. Lane, Consumer Affairs Officer, Food and Drug Administration, 900 Madison Ave., Baltimore, MD 21201, 301-962-3731.

Supplementary information: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: June 10, 1983.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-16275 Filed 6-14-83; 11:39 am]

BILLING CODE 4160-01-M

---

[Docket No. 83C-0051]

## Custom Tint Laboratories, Inc.; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Custom Tint Laboratories, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of six dyes in coloring contact lenses.

**FOR FURTHER INFORMATION CONTACT:** Rudolph Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 706(b)(1), 74 Stat. 399–402 as amended (21 U.S.C. 376(b)(1))), notice is given that a petition (CAP 3C0169) has been filed by Custom Tint Laboratories, Inc., 6020 Six Forks Rd., Raleigh, NC 27609, proposing that the color additive regulations be amended to provide for the safe use of an orange dye, dibromodibenzo (b,def)chrysene-7,14-dione; a brown dye, 16,23-dihydrodinaphtho(2,3-a:2',3'-i)naphth(2',3':6,7)indolo (2,3-c)-carbazole-5,10,15,17,22,24-hexone; a yellow dye, *N,N'*-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide; an orange dye, 6,6'-diethoxy-2,2'-(3H,3'H) bibenzo(b)thiophene-3,3'-dione; a blue dye, 7,16-dicholoro-6,15-dihydro-5,9,14,18anthrazinetetrone; and a green dye, 16,17-dimethoxydinaphthol(1,2,3-cd:3',2',1'-lm)perylene-5,10-dione in coloring contact lenses.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: June 9, 1983.

Sanford A. Miller,
*Director, Bureau of Foods.*

[FR Doc. 83-16274 Filed 6-16-83; 8:45 am]
BILLING CODE 4160-01-M

---

[Docket No. 83C-0167]

## Ethicon, Inc.; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ethicon, Inc., has filed a petition proposing to amend the color additive regulations to provide for the safe use of D&C Blue No. 6 to color polydioxanone synthetic absorbable sutures.

**FOR FURTHER INFORMATION CONTACT:** Blondell Anderson, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 706(b)(1), 74 Stat. 399–402 as amended (21 U.S.C. 376(b)(1))), notice is given that a petition (CAP 3C0176) has been filed by Ethicon, Inc., Route 22, Somerville, NJ 08876, proposing that Part 74 (21 CFR 74) be amended to provide for the safe use of D&C Blue No. 6 to color polydioxanone synthetic absorbable sutures.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: June 9, 1983.

Sanford A. Miller,
*Director, Bureau of Foods.*

[FR Doc. 83-16271 Filed 6-16-83; 8:45 am]
BILLING CODE 4160-01-M

---

[Docket No. 79D-0465]

## Human, Biological, and Animal Drugs and Medical Devices; Availability of Draft Guidelines for Use of the Limulus Amebocyte Lysate (LAL) Test; Extension of Comment Period

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to July 31, 1983, the comment period for the notice announcing the availability of a draft guideline entitled "Draft Guideline for Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices." The draft guideline sets forth acceptable conditions for use of the Limulus Amebocyte Lysate (LAL) test and describes procedures for using this methodology as an end-product endotoxin test for human injectable drugs (including biological products), animal injectable drugs, and medical devices. FDA is taking this action in response to a request for an extension of the comment period.

**DATE:** Comments by July 31, 1983.

**ADDRESS:** Requests for a copy of the draft guideline and written comments regarding the draft guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

*Human Drugs*

Terry E. Munson, National Center for Drugs and Biologics (HFN-325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6007.

*Biological Products*

Michael L. Hooton, National Center for Drugs and Biologics (HFN-813), Food and Drug Administration, 8800 Rockville Pike, Bethesda MD 20205, 301–443–1306.

*Animal Drugs*

Patricia Cushing, Bureau of Veterinary Medicine (HFV-143), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1788.

*Medical Devices*

Virginia C. Ross, National Center for Devices and Radiological Health (HFK-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 29, 1983 (48 FR 13096), FDA issued a notice announcing the availability of a draft guideline entitled "Draft Guideline for Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices." The draft guideline sets forth acceptable conditions for use of the LAL test and describes procedures for using this methodology as an end-product endotoxin test for human injectable drugs (including biological products), animal injectable drugs, and medical devices. The draft guideline is intended to inform interested persons of these acceptable principles which may be used in lieu of the currently official rabbit pyrogen test and was made available for public comment to provide the agency with views to be considered in its development of a final guideline. Interested persons were given to June 27, 1983, to comment on the draft guideline.

In response to the notice, Bayer AG requested an extension of the comment period until July 31, 1983. Bayer AG stated that the **Federal Register** notice announcing the availability of the draft guideline was not available to foreign manufacturers until 5 weeks after publication in the United States and, consequently, the 90-day comment period specified in the notice is unreasonable for foreign manufacturers.

FDA has carefully considered the request. The agency does not accept the argument that the 90-day period