NADA no.	Drug name	Sponsor name and address
121–291	Enflurane liquid (anesthetic)	Ohmeda, Inc., Pharmaceutical Products Division, P.O. Box 804, Liberty Corner, NJ 07938–0804.
121–813	Styrylpyridinium, diethylcarbamazine film-coated tablets	Bayer Corp.
133–509	Pyrantel tartrate Type A medicated articles	Hubbard Milling Co.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 6–462, 10–540, 11–380, 12–054, 12–103, 12–392, 12–598, 15–161, 15–965, 30–045, 34–394, 35–263, 45–287, 48–645, 49–555, 91–628, 93–372, 94–402, 95–078, 96–031, 100–201, 100–356, 100–670, 101–078, 120–327, 120–670, 121–291, 121–813, and 133–509, and all supplements and amendments thereto is hereby withdrawn, effective July 15, 1996.

In a final rule published elsewhere in this issue of the Federal Register, FDA is removing 21 CFR 520.500, 520.620a, 520.620b, 520.1520, 520.2022, 520.2160a, 520.2160b, 520.2160c, 520.2160d, 520.2480, 520.2520c, 520.2520d, 522.281, 522.740, 522.2022, 522.2480, 529.810, 558.367, and 558.565, and amending 21 CFR 520.580, 520.622a, 520.622b, 520.2520a, 558.185, 558.485, 558.625, and 558.630 to reflect the withdrawal of approval of the above mentioned NADA's.

Dated: June 3,1996.

Michael J. Blackwell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 96–16887 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0159]

Compounding of Drugs for Use in Animals; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Compliance Policy Guide (CPG) section 608.400 entitled ''Compounding of Drugs for Use in Animals.'' The purpose of this CPG is to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. The CPG contains information that may be useful to industry and the public. The text of the CPG is included in this notice. This CPG does not bind FDA, nor does it create or confer any rights, privileges, benefits, or immunities on or for any person.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals'' to the Industry Information Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of CPG section 608.400 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Richard E. Geyer, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1764.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals.'' The purpose of this CPG is to provide clear policy and regulatory guidelines to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. It also contains information that may be useful to industry and to the public.

The Federal Food, Drug, and Cosmetic Act (the act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. However, veterinarians and pharmacists do manipulate drugs (e.g., combine or dilute finished dosage forms, prepare finished dosage forms from bulk drug substances, or prepare injectables from powdered oral dosage forms) to obtain products that differ from the starting materials.

FDA acknowledges the use of compounding within certain areas of veterinary practice. The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics. While the agency acknowledges the need for compounding under certain circumstances, it is also aware of recent adverse reactions and animal deaths caused by compounded drug products and is concerned about the risks associated with compounding practices in veterinary medicine. In addition, the agency is greatly concerned about pharmacies that produce large quantities of unapproved new animal drugs that are essentially copies of FDA-approved products. These pharmacy products are actively advertised and promoted, and sometimes are priced lower than the approved product. The firms claim that they are practicing within the scope of their State licenses. However, it is apparent that some of these firms use their pharmacy licenses to circumvent the entire drug approval process, and are mass marketing products that have been produced under little or no quality control, manufacturing standards to ensure purity, potency, and stability.

When the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) is implemented and becomes effective, it will allow compounding from approved drugs because it will permit the extralabel use of approved animal and human drugs. Extralabel use, including compounding, under AMDUCA will be subject to conditions specified by the implementing regulations. The scope of compounding made legal upon the effective date of AMDUCA will be addressed by those regulations.

CPG section 608.400 represents FDA's current position and interpretation of the act. The CPG is intended to provide clear guidance to FDA field and headquarters staff and also could

provide information to the animal health industry. However, this document, which is intended merely for internal FDA guidance, does not bind FDA, nor does it create or confer any rights, privileges, benefits, or immunities on or for any persons. FDA may reconsider its position at a later date in light of comments received or other data or information which comes to the attention of the agency.

COMPLIANCE POLICY GUIDE [1]

CHAPTER - 6

SUB CHAPTER - 600

Sec. 608.400 Compounding of Drugs for Use in Animals

Background:

The Federal Food, Drug, and Cosmetic Act (the Act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. However, veterinarians and pharmacists do manipulate drugs (e.g., combine or dilute finished dosage forms, prepare finished dosage forms from bulk drug substances, or prepare injectables from powdered oral dosage forms) to obtain products that differ from the starting materials.

There is a potential for causing harm to public health and to animals when drug products are compounded, distributed, and used in the absence of adequate and well-controlled safety and efficacy data, adherence to the principles of contemporary pharmaceutical chemistry and current good manufacturing practices.

The Agency acknowledges the use of compounding within certain areas of veterinary practice. The practice of veterinary medicine requires products to treat many conditions in a number of different species, some of which have unique physiological characteristics. FDA, other federal, state agencies, and producer groups encourage drug sponsors to obtain approvals for all new animal drugs.

While the Agency acknowledges the use of compounding under certain circumstances, it is also aware of adverse reactions and animal deaths caused by compounded drug products and is concerned about the risks associated with compounding practices in veterinary medicine. An example is the recent death of cattle due to the presence of endotoxin in a parenteral product prepared from spectinomycin approved for oral use. In addition, the Agency is greatly concerned about pharmacies that produce large quantities of unapproved new animal drugs that are essentially copies of FDA-approved products. These pharmacy products are actively advertised and promoted, and sometimes are priced lower than the approved product. The firms claim that they are practicing within the scope of their state licenses. However, it is apparent that some of these firms use their pharmacy licenses to circumvent the entire drug approval process, and are mass marketing products which have been produced with little or no quality control, manufacturing standards to ensure purity, potency and stability.

The pharmacokinetics and depletion times for residues from compounded products are not known and the assigning of extemporaneous withdrawal times may result in potentially harmful residues in food. Excipients and vehicles from unapproved or unknown origins may pose additional risks.

Section 510(g)(1) of the Act exempts from the registration requirements licensed pharmacies which do not compound drugs except exclusively within the regular course of their business of dispensing or selling drugs at retail. Section 510(g)(2) exempts from the registration requirements licensed practitioners who manufacture, prepare, propagate, compound, or process drugs during the regular course of business of dispensing drugs at retail. The Act and regulations do not, however, exempt such practitioners or pharmacists from the approval requirements in the new animal drug provisions of Sections 501(a)(5) and 512. Therefore, compounding allowed under the Act is limited to the preparation of drug products which do not meet the definition of new animal drugs. In the absence of an approved new animal drug application (NADA), the compounding of a new animal drug from any article, including an approved or unapproved finished human or animal drug, or a bulk drug, results in an adulterated new animal drug in violation of section 501(a)(5).

Compounding from Approved Dosage Form Drugs: When the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) goes into effect, it will allow the ''extra-label'' use of approved animal and human drugs. It will also allow compounding from those approved drugs. Under AMDUCA ''extra-label'' use, including compounding, will be subject to conditions specified by regulation. AMDUCA will become effective upon promulgation of the regulations. The scope of compounding made legal upon the effective date of AMDUCA will also be addressed by the regulations. The proposed regulations were published in the Federal Register on May 17, 1996. They have no effect until finalized.

Compounding from Bulk Drugs: Two Federal Appeals Court decisions, *United States v. Algon Chemical Inc.*, 879 F.2d 1154 (3d Cir. 1989), *United States v. 9/1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988), affirmed the FDA position that the Act does not permit veterinarians to compound unapproved finished drug products from bulk drugs, *unless the finished drug is not a new animal drug.* The principle established by the court applies equally to compounding by pharmacists. However, one of the courts acknowledged the Agency's policy that, *if the need is great and the risk small*, the Agency may exercise regulatory discretion with respect to veterinarians compounding from approved drugs under Compliance Policy Guide (CPG) 615.100, *Extra-label Use of New Animal Drugs in Food-Producing Animals.*

Definitions:

The Act and accompanying regulations do not define compounding as different from other processing of drug compounds.

Bulk drug is an active ingredient (in unfinished form) intended for manufacture into finished dosage form drug products (from *United States v. Algon Chemical Inc.*, 879 F.2d 1154 (3d Cir. 1989)). See also 21 CFR 207.3(a)(4). Bulk drugs (or ''bulk drug substances'') may be supplied in various size containers and may or may not meet USP standards.

Compounding is defined, for the purposes of this CPG, as any manipulation to produce a dosage form drug other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product, for example, the reconstitution of a sterile powder with sterile water for injection.

Compounding ordinarily not subject to regulatory action, is defined as compounding by a licensed pharmacist or veterinary practitioner, when the criteria described in this document are met, within the confines of a legitimate practice. However, this document shall not be construed to bind the FDA or otherwise constrain its enforcement discretion. In addition, this document imposes no new obligations.

Compounding subject to regulatory action, is defined as compounding by a licensed pharmacist or other practitioner, when the criteria described in this document are not met, even if it is otherwise within the confines of a legitimate practice. Compounding outside the confines of a legitimate pharmacy or veterinary practice, whether by a pharmacist, veterinarian or other party, is subject to regulatory action.

''*Legitimate practice*'' is defined as follows:

(a) Pharmacist: A person licensed and operating in conformity with state law, and dispensing in response to a valid prescription.

(b) Veterinarian: A person licensed and operating in conformity with state law, and prescribing or dispensing in response to a valid Veterinarian-Client-Patient Relationship (VCPR.)

Valid Veterinarian-Client-Patient Relationship (VCPR)

A valid VCPR exists when: (1) the veterinarian assumes the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) agrees to follow the instructions of the veterinarian; and (2) the veterinarian has sufficient knowledge of the circumstances to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s), i.e., the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Source: American Veterinary Medical Association.

[1] This Update to the Compliance Policy Guides Manual (March 1995 edition) is a new CPG. This update will be included in the next printing of the Compliance Policy Guides Manual. The statements made in the CPG are not intended to create or confer any rights, privileges, or benefits on or any private person, but are intended for internal guidance.

Policy:

Circumstances exist when it may be necessary for a veterinarian to compound, or direct for a pharmacist to compound, an article that will result in an unapproved new animal drug. There is occasionally a need to utilize drugs labeled for human use, and much less commonly, bulk drug substances, for compounding into an appropriate dosage form. Some examples of these situations include: combinations of anesthetic drugs for titrated administration; preparation of dilute dosage forms for small, young, or exotic species patients; and usage of some antidote preparations. The Agency will exercise regulatory discretion and ordinarily would not take regulatory action against violations of the Act resulting from compounding an unapproved new animal drug if a determination is made that, in order to provide appropriate medical therapy, it is necessary to compound a new animal drug when the following conditions are met:

(1) A legitimate medical need is identified (the health of animals is threatened and suffering or death would result from failure to treat the affected animals),

(2) There is a need for an appropriate dosage regimen for the species, age, size, or medical condition of the patient, and

(3) There is no marketed approved animal drug which, when used as labeled or in an ''extra-label'' manner in conformity with criteria listed in CPG 615.100, or human-label drug, when used in conformity with criteria listed in CPG 608.100, may treat the condition diagnosed in the available dosage form, or there is some other rare extenuating circumstance. (For example, the approved drug cannot be obtained in time to treat the animal(s) in a timely manner, or there is a medical need for different excipients.)

After making the above determinations, the following criteria should be met and precautions observed:

(1) Dispensing by a licensed veterinarian; or the receipt of a valid prescription of a licensed veterinarian by a pharmacist. Dispensing should be within the confines of a valid veterinarian-client-patient relationship. Veterinarians should exercise professional judgment to determine when compounding requires the services of a pharmacist. Professional assistance is appropriate when the complexity of compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(2) The veterinarian takes measures to ensure that:

(a) When used in food-producing animals: no illegal residues occur; a significantly extended time period is assigned for drug withdrawal; and steps are taken to assure that the assigned time frames are observed;

(b) The safety and efficacy of the compounded new animal drug is consistent with current standards of pharmaceutical and pharmacological practices, e.g., known incompatibilities are avoided;

(c) Appropriate steps are taken to minimize risk of personnel exposure to potentially harmful ingredients in the preparation process; and

(d) Procedures are instituted to assure that appropriate patient records for the treated animals are maintained.

(3) All drugs dispensed to the animal owner by the veterinarian or a pharmacist, bear labeling information which is adequate to assure proper use of the product. The following label information should be included:

(a) Name and address of the veterinary practitioner;

(b) the active ingredient or ingredients;

(c) the date dispensed and the expiration date, which should not exceed the length of the prescribed treatment except in cases where the veterinarian can establish a rationale for a later expiration date;

(d) directions for use specified by the practitioner, including the class/species or identification of the animals; and the dosage, frequency, route of administration, and duration of therapy;

(e) cautionary statements specified by the veterinarian and/or pharmacist (this would include all appropriate warnings necessary to ensure safety of human operators handling the finished drug, especially if there are potential hazards of exposure to any components);

(f) the veterinarian's specified withdrawal/discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s) (while the veterinarian must set the withdrawal time, the veterinarian in doing so may use relevant information provided by a dispensing pharmacist although the veterinarian retains ultimate responsibility);

(g) if dispensed by a licensed pharmacist, the name and address of the dispenser, serial number and date of order or its filing;

(h) if dispensed by a veterinarian, the serial number; and

(i) any other applicable requirements of state or federal law.

(4) The pharmacist adheres to the National Association of Boards of Pharmacy Good Compounding Practices (GCP), or to equivalent state good compounding practice regulations, except where provisions conflict with this CPG. Among other practices, pharmacists should keep records of compounding formulas, logs of compounded items and specific ingredients, record of assurance of quality of raw materials; and information on adverse effects and product failures. Pharmacists should label compounded products with expiration dates that do not exceed the prescribed period of treatment, and with withdrawal times furnished by the prescribing veterinarian.

Veterinarians and pharmacists who compound or prescribe compounded medicaments and pharmacists who compound medicaments according to these guidelines criteria set out above would be considered to be engaged in extemporaneous compounding not ordinarily subject to regulatory action.

Regulatory Action Guidance:

Investigations will be conducted in coordination with state officials as specified in the October 26, 1995 letter from Associate Commissioner for Regulatory Affairs (FDA) and Executive Director, National Boards of Pharmacy, to state pharmacy and drug regulatory officials, and FDA officials.

FDA actions based on violative conditions will be consistent with state laws and regulations to the extent possible. Deviations from GCP may be deferred to state authorities for action.

In general, the agency will place its highest regulatory priority on compounding products for use in food animals.

A. The following situations would likely indicate compounding subject to regulatory action and the existence of one or more would ordinarily be of high regulatory priority.

-Preparation for sale of *large* quantities of unapproved new animal drugs on an *ongoing* basis and where no valid *medical need* or VCPR exists. Compounding very limited quantities in anticipation of future need is acceptable provided that a history of past need can be documented;

-Compounding of medicaments that are essentially similar to FDA-approved products except in rare instances where a legitimate need can be established, for example, to treat animals on a timely basis or to avoid problems caused by certain excipients.

-Substitution or recommendation by a pharmacist of a compounded medicament for a prescription instead of using an FDA-approved product;

-Compounding from bulk drugs for use in food animals, with the rare exception of those medicaments that are permitted to be compounded by the Center for Veterinary Medicine (CVM) through compassionate regulatory discretion or other means (such as certain antidotes, large volume electrolyte products and other substances). Because these items may be revised, an official contact office at CVM has been designated to provide current information. That contact office is HFV–236, Case Guidance Branch, Division of Compliance, (301) 594–1785.

-Preparation for sale of unapproved new animal drugs on any scale which employ fanciful or trade names, colorings or other additives, or in any way imply that the products have some unique effectiveness or composition;

-Advertising, promotion, display, sale, or other means of marketing, prepared unapproved new animal drugs; and soliciting business to compound specific drug products, product classes or therapeutic classes of drug products;

-Offering compounded medicaments at wholesale to other state licensed veterinarians or pharmacists or other commercial entities for resale;

-Offering financial incentives such as rebates and consulting fees; and

-Dispensing of large quantities of compounded medicaments, where questions of stability of the finished product would arise;

-Failing to follow good compounding practices, including current standards of pharmaceutical and pharmacological practices, as described above;

-Labeling a product with an expiration date that exceeds the prescribed treatment period;

-Labeling a product with a withdrawal time established by the pharmacist instead of the veterinarian;

-Dispensing a disproportionate amount of compounded products out of state. The primary concern is the difficulty of maintaining proper relationships, for

example, pharmacist/veterinarian/client and VCPR. Rare instances of specialized compounding to meet emergency needs would not be considered disproportionate.

B. The following situations would indicate excessive risk to public health or to animals, or an otherwise adverse risk/benefit ratio, of high regulatory priority:

-Instances where illegal residues occur in meat, milk, eggs, honey, or aquaculture products and the residues were caused by the use of a compounded drug in association with the violation being investigated;

-Compounding of medicaments for food-producing animals, especially those used in lactating dairy animals, which cause a significant risk of illegal residues because, for example, withholding times have not been established by the veterinarian using adequate scientific information; and

-Preparation of drug products that are essentially similar to products that have been removed from the market due to regulatory concerns, for example, chloramphenicol, dimetridazole, DES in food animals.

C. The following activities would indicate compounding subject to regulatory action, and possibly of high regulatory priority. However, guidance from CVM should be solicited to assess the potential public health threat and/or animal safety (i. e., risk vs benefits).

-Instances where animals have been harmed or their safety unnecessarily compromised, such as compounding a nonsterile product for parenteral or ophthalmic administration where a sterile product is indicated, or other instances of not adhering to good compounding practices.

-Compounded substances that do not bear the required label information, including the name of the authorizing veterinarian, the active ingredients, directions for use, cautionary statements, and withdrawal times.

D. The following compounding situations would not ordinarily be considered for regulatory action. Appropriate state and local practice and pharmacy laws must be adhered to, however.

-Compounding for non-food animals and minor food animal uses where public health and animal safety have not been threatened, and are of great need and small risk. This would include such common practices as: veterinarians' combining agents for anesthesia, large volume parenterals, preparing appropriate dosage-forms for the size of the patient in question, ''animal-side'' compounding, and other similar common practices that are widely accepted in the day to day treatment of animal patients.

-Compounding from bulk drug substances for use in nonfood animals, including animals in public and private aquaria, when animal health is not threatened, and there is not a significant risk of diversion of the bulk drugs or compounded drugs for use in food animals. Bulk drug substances would ordinarily be expected to be in small packages that meet or exceed USP standards; see definition of ''bulk drugs'' above. Compounding should be performed in accordance with current standards of pharmaceutical practice (including referral to compendial monographs or established pharmacy textbooks).

If circumstances exist on a case-by-case basis that indicate otherwise, the Field should request guidance from CVM before considering regulatory action. The preceding is not intended to be a complete list of activities relating to compounding; there may be other factors which are appropriate when assessing an individual case.

Guidance for Charging Violations:

A warning letter is ordinarily the first choice of action, when referral to state authorities is not appropriate. Injunction would be the usual choice of court action, although seizure should be considered in the case of high priority drugs such as chloramphenicol or DES intended for use in food animals. Criminal action can be considered in egregious situations.

Compounded drugs subject to regulatory action under this policy will ordinarily be charged as unapproved new animal drugs, violative under Section 501(a)(5). Deviations from GCP, if not subject of state action will ordinarily be charged under Section 501(a)(2)(b). The tissue residue violations are covered under Section 402(a)(2)(D).

Dated: June 26, 1996.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 96–16973 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0184]

Life Technologies, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Life Technologies, Inc., has filed a petition proposing that the food additive regulations be amended to provide for a change in the level of reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use.

DATES: Written comments on the petitioner's environmental assessment by August 2, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6A4500) has been filed by Life Technologies, Inc., 8400 Helgerman Ct., Gaithersburg, MD 20874. The petition proposes to amend the food additive regulations in § 173.25 *Ion-exchange resins* (21 CFR 173.25) to provide for a change in the level of the reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use. The amendment proposes that the amount of epichlorohydrin plus propylene oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose. The current regulation provides that the amount of epichlorohydrin plus propylene oxide employed does not exceed 61 percent by weight of the starting quantity of cellulose.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 2, 1996, submit to the Dockets Management Branch (address above) written comments. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, 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).

Dated: May 31, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–16975 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F