

# APPMA

American Pet Products Manufacturers Association, Inc.

September 5, 1997

Dockets Management Branch [HFA-305]  
Food and Drug Administration  
12420 Parklawn Dr., Rm. 1-23  
Rockville, MD 20857

9014 '97 SEP -8 AM 1:51

Re: **Docket No. 97N-0217**, Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses of New Animal Drugs, 21 CFR Chapter 1, 62 Fed. Reg. 120 [June 23, 1997].

Dear Sir/Madam:

The American Pet Products Manufacturers Association (APPMA) is a trade association representing approximately 500 pet product manufacturers. Close to 40% of our members are small manufacturers, i.e., with gross annual sales of less than \$500,000 nationally. We represent larger manufacturers as well. Our industry employs more than 250,000 individuals in the manufacturing, distribution and marketing of pet products, many of which, including remedies for nonfood fish, reptiles, birds, and small mammals, are necessary for the continued health and comfort of the pet. Additionally, a recent national survey showed that there are approximately 260 million pets in the United States and that 59% of American households have at least one pet.

APPMA urges the expeditious passage of legislative and regulatory options that will facilitate the approval of new animal drugs intended for use in minor species and for minor uses, as contemplated in the Animal Drug Availability Act of 1996 [ADAA], particularly for the nonfood minor animal species. The economics of the current animal drug approval process effectively preclude FDA-approved drugs for treatment of nonfood minor species, since the standards are essentially the same for food animal species and nonfood species. This process is prohibitively expensive as applied to remedies for nonfood minor species because of the relatively small volume of sales for any one drug. Facilitating drug approvals for these species will bring about a much needed increase in the availability of approved remedies which are needed to address

97N-0217

P  
C14

## BOARD OF DIRECTORS

President  
**Bart E. Schillaci**  
The Brampton Company

First Vice President  
**Clark Allen**  
Combe Incorporated

Second Vice President  
**Dennis Curley**  
Lazy Pet Products

Third Vice President  
**L. Bryant Barry, CSE**  
Wellmark International

Secretary/Treasurer  
**James W. Wingate**  
MIDWEST Homes for Pets

## Directors

**Robert A. Cuthbert**  
Lambert Kay

**Craig DeWalt**  
California Aquarium  
Supply Corporation

**Terry Elter**  
Ryder Corporation

**Harvey Feinberg**  
Perfecto Manufacturing Inc.

**Gary Hirschberg**  
Vo-Toys, Inc.

**David C. Horton, Jr.**  
Horton Company Inc.

**Kenneth Humpert**  
Finny World Class  
Pet Products, Inc.

**Allan L. Levey**  
The Hartz Group

**Edmund Mowka**  
Aquarium Systems, Inc.

**Royal D. Soward, Jr.**  
Zema Corporation

**Mark Stern**  
Eight In One Pet Products

**EXECUTIVE STAFF**

Executive Vice President  
**William D. Schoolman**

General Counsel &  
Director Legislative Affairs  
**Avis W. Effinger, Esq.**

Director of Member Services  
**Luann O'Brien**

Director of Public Relations  
**Funda Alp**

page 2  
September 5, 1997

the scarcity of approved drugs for nonfood minor animal species.

APPMA is confident that a reasonable, effective and affordable drug approval process can be developed that will protect the public health, provide assurance of drug efficacy, and provide manufacturers of drugs with the ability to develop and market safe and effective treatments. This will in turn benefit American consumers by providing them with a wider range of safe and effective products for assurance and maintenance of the health, safety and comfort of their pets.

In developing new animal drug approval processes for minor species, the Food and Drug Administration [FDA] must, first and foremost, differentiate between drugs intended for food animals and those intended for nonfood animals. The nonfood minor species group should also be subclassified to reflect the type of animals, relative abundance, and use in society. One such subgroup should be nonfood minor animals maintained as companion pets such as birds, reptiles, amphibians, fish and small mammals (other than dogs and cats).

Furthermore, "crop grouping" should be permitted for the purpose of drug approvals for those nonfood minor animal species maintained as pets, including numerous, diverse genera and species, e.g., ornamental aquarium and garden pond fish. Any drug approval process for nonfood minor animal species which continues the use of the current species-specific regulatory approach requiring different approvals for each species will be prohibitively expensive for manufacturers and for consumers.

Drug uses in these nonfood minor animal species maintained as pets present minimal or no human health concerns. APPMA supports legislative and regulatory changes that will grant FDA the authority to create alternative new animal drug approval processes for minor species and for minor uses, and is committed to continued efforts to provide safe and effective drugs for nonfood animals maintained as pets.

APPMA's recommendations and answers to questions posed in FDA's notice are provided in the enclosed "Comments." While these comments are primarily addressed to drug approvals for a subgroup of nonfood minor animal species maintained as pets [ornamental aquarium and garden pond fish], the basic concepts are equally applicable to other nonfood minor animal species maintained as pets.

While drugs are available and approved for many animal species of higher commercial value, the economic justification for obtaining drug approvals for nonfood minor species maintained

page 3  
September 5, 1997

as companion pets does not exist under the current regulatory scheme because of the typically small volume of sales for any one drug. In order to permit approval of safe and effective therapeutic agents for use in these nonfood minor species, appropriate drug approval procedures must be created. Without access to approved animal drugs, these animals may experience unnecessary suffering and/or death due to diseases which are treatable by therapeutic agents which are unavailable to the consumer solely because of prohibitive cost of drug approvals.

The ADAA provides the opportunity for legislative and regulatory options that will facilitate the approval of new animal drugs intended for use in minor species and for minor uses. We urge the FDA to take advantage of this opportunity.

We appreciate the opportunity to express our opinion on this critically important issue.

Sincerely yours,



Avis W. Effinger, Esq.

General Counsel

Enclosure

# APPMA

---

American Pet Products Manufacturers Association, Inc.

September 5, 1997

## COMMENTS

Docket No. 97N-0217, Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses of New Animal Drugs, 21 CFR Chapter 1, 62 Fed.Reg. 120 [June 23, 1997].

[**Note:** These comments are organized according to the format suggested in the Federal Register Notice. While these recommendations and answers to questions posed in the U. S. Food and Drug Administration's [FDA] notice are primarily addressed to drug approvals for a subgroup of nonfood minor animal species maintained as pets, i.e., ornamental aquarium and garden pond fish, the basic concepts are equally applicable to other nonfood minor animal species maintained as pets such as birds, reptiles, amphibians, and small mammals (other than dogs and cats).]

## Introduction:

The culture and keeping of ornamental aquarium and garden pond fish dates back beyond the founding of this nation. Today, the domestic culture of thousands of species of fish is practiced in warm and cool water conditions for the benefit of fish hobbyists who enjoy caring for these animals as pets. The industry and the hobby have evolved utilizing tried and tested management techniques which include the use of medical treatments for different diseases common to fish. While drugs are available and approved for many animal species of higher commercial value, the economic justification for obtaining drug approvals for nonfood minor species maintained as companion pets does not exist under the current regulatory scheme because of the typically small volume of sales for any one drug. In order to permit approval of safe and effective therapeutic agents for use in these nonfood minor species, appropriate and affordable drug approval procedures must be created.

The 1996 Animal Drug Availability Act [ADAA] provides the mechanism by which FDA rules may be written to protect human and animal health and provide an effective and affordable drug registration process for nonfood minor species. APPMA urges the FDA to take advantage of this opportunity.

In order to reduce minor animal species suffering and/or death from treatable diseases and to limit transmission of zoonotic diseases, approved therapeutic agents are needed. The economics of the current New Animal Drug

Approval process [NADA] effectively preclude FDA-approved drugs for treatment of nonfood minor animal species, since the standards are essentially the same for food animal species and nonfood species. This process is prohibitively expensive as applied to nonfood minor species because of the relatively small volume of sales for any one drug. The current drug approval process is clearly regressive in its inability to address the needs of diverse populations of minor animal species and the needs of animal drug manufacturers. Ultimately, the current process does not account for the great differences in the relative risks to human health that exist in the drug uses for food animals and nonfood animals and does not serve the best interests of the public.

FDA must be given the flexibility to develop efficient new animal drug approval processes for different classes of minor species, particularly the nonfood minor species which are maintained as pets. Authority should be provided to FDA to work with these minor species producer groups and drug manufacturers to create new approval processes that are both designed to protect human and animal health and to provide an affordable process for approval of drugs.

### **Responses to questions posed in the Federal Register Notice.**

#### **A. Scope.**

FDA seeks comments on the criteria found at 21 CFR s. 514.1(d)(1) for the determination of a minor species or a minor use.

#### **Comment:**

For the purpose of developing new animal drug approval processes, minor animal species should be subclassified into minor species that are intended for use as food and those that are not. The nonfood minor animal species group should also be further subclassified to reflect the type of animals, relative abundance, and use in society. One such subclassification should be nonfood animals maintained as companion pets such as birds, reptiles, amphibians, fish and small mammals (other than dogs and cats). Drug uses in these nonfood minor animal species maintained as pets pose minimal or no human health concerns. Furthermore, "crop grouping" should be permitted for those nonfood minor animal species maintained as pets which include numerous, diverse genera and species, e.g., ornamental aquarium and garden pond fish.

#### **B. Creating Additional Statutory Authority.**

**Question 1.** Should there be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor uses?

#### **Comment:**

**Yes,** there should be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor

uses.

Economic considerations require different standards for minor species or minor uses in order to insure the availability of effective treatments. The market is relatively small for most minor species drugs, and the costs of compliance with the "full-blown" drug approval processes make treatment of diseases in these animals prohibitively expensive.

Examples:

- i. If a drug approval exists for a food fish, the approved label should be automatically extended [with appropriate approvals from the prior registrants] to nonfood fish.
- ii. "Crop grouping" [the use of representative species] should be permitted for those nonfood minor animal species maintained as pets which include numerous, diverse genera and species, e.g., ornamental aquarium and garden pond fish.
- iii. Animal drug approvals should be granted for ornamental aquarium and garden pond fish, based upon such information as:
  - Evidence of historical use as provided in published literature or current texts.
  - Review of drug labels and drug use by a panel of experts.
  - Modified animal safety and effectiveness protocols using representative test species.

**Question 2.** Should there be different standards for human food safety for new animal drugs intended for minor species and for minor uses? If so, what should those standards be?

**Comment:**

**Yes,** there should be different standards for human food safety for new animal drugs intended for minor species and for minor uses, particularly for nonfood minor animal species maintained as pets.

Food safety standards should not be required for nonfood minor species. When low concentrations of drugs are used in appropriate forms to treat these species, there is minimal risk to human health. For example, there are no tissue residue risks involved, as might be the case with other species.

**Question 3.** Should the standards be the same for all minor species or minor uses? Why?

**Comment:**

**No,** the standards should not be the same for all minor species or minor uses. Minor species should be divided into food and nonfood species, and the nonfood minor species should be further subdivided to reflect the relatively low drug-related health risks to humans posed by treatment of such species, e.g.,

ornamental aquarium and garden pond fish. An approval process could be developed to address the specific needs of these animals.

Minor uses of drugs should be available for major and minor animal species. Minor uses in nonfood minor species and subclassifications of these species should be considered on a case by case basis, with reduced drug approval requirements ensuring target animal safety and efficacy whenever human health concerns are not implicated.

**Question 4.** Should products be labeled to reflect the use of different standards? If not, why not?

**Comment:**

Yes, products should be labeled to reflect the use of different standards. For example, nonfood fish drugs should be labeled "not for human consumption or for use in animals intended for human consumption."

**Question 5.** If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards, how would appropriate doses be determined, and how would residue depletion and withdrawal times for food animals be determined?

**Comment:**

If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards:

Appropriate doses could be determined as follows for ornamental nonfood fish, for example: historical use, literature sources and/or a panel of experts familiar with the nonfood fish drug use could be used to review the suggested range of dosage recommendations. If no suggested dosage exists, a modified dose determination and efficacy testing protocol could be developed and used.

Residue depletion and withdrawal times for food animals are, by definition, not applicable to ornamental nonfood fish.

**Question 6.** Would sponsors and users accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket target animal safety and effectiveness studies for new animal drugs for minor species or minor uses? Should a drug approved under such a mechanism bear labeling that reflects its conditional status?

**Comment:**

In the case of drug approvals for nonfood ornamental aquarium and garden pond fish, it would be best to develop a specific approval process for this subcategory of nonfood minor species, and have manufacturers proceed by submitting the appropriate information developed by FDA and the industry.

**Question 7.** Should the act be amended to allow FDA to accept foreign reviews or approvals of new animal drugs for minor species or for minor uses? How should Congress or FDA determine whether the reviews or approvals of a particular country or countries are acceptable as a basis for approval of uses for minor species or for minor uses?

**Comment:**

Foreign reviews and approvals should be used as part of the drug approval process. Many foreign countries have animal drug approval processes comparable to the FDA process. Data from countries with drug approval processes acceptable to the FDA should be acceptable to use in submissions of nonfood minor species drug approvals. Determination of acceptable drug reviews and approvals for countries with limited regulatory oversight, might best be accomplished through the use of industry and expert review and comment.

**Question 8.** Should the current statutory standard for new animal drug approval for drugs intended for minor species or minor uses or any alternative standards be implemented through a primary review process external to the agency? If so, how might this process be administered? Who should pay for the external reviews?

**Comment:**

Yes, because of the diversity of minor species and minor use drugs, FDA may not have the available time or knowledge to expeditiously review and develop testing protocols. As an alternative to an internal FDA process, an external panel of recognized and agreed upon experts could be used to review materials, such as label language, historical use data, foreign data or existing literature dosage recommendations. This external process could be used by a manufacturer in order to expedite the process.

An alternative process might be administered by an industry group or by individual sponsors. One of these entities might prepare a "primary review" submission for label language, minor use drug approval, etc., and nominate a panel of experts to review data, consider laboratory testing, or suggest another appropriate procedure. FDA could then review the proposals, and, in consultation with the industry or individual sponsor, modify the submission as needed for FDA approval prior to implementation of the process. FDA would review the findings as the basis for drug approval.

In order to expedite the process, the industry or an individual sponsor might choose to pay for an alternative external review process.

**Question 9.** Could determinations of animal safety and effectiveness by expert panels or compendia be used to support drug approvals for minor species and minor uses? If so, what information would serve as the basis for such determinations? Should the determinations of these panels or other information

be used to issue monographs or similar standards? Who would draft monographs or similar standards and why?

**Comment:**

Yes, determinations of animal safety and effectiveness by expert panels or compendia could be used to support drug approvals for minor species and minor uses.

The information needed would vary with the drug, existing approval status for the drug for other species, the minor species and minor use being considered, history of use, concentration and volume of drug to be marketed, etc. In the case of nonfood ornamental aquarium and garden pond fish, a generic protocol could be used for most drugs having historical use, with additional requirements for unique drugs.

If a sponsor or group of sponsors funds the expert panel, the results of the panels findings should remain with the sponsor(s) for submittal to FDA. However, the intent and use of such a "monograph" needs further definition before a meaningful comment can be made on this issue.

C. Administrative and Regulatory Changes.

**Question 10.** Should there be different standards for manufacturing of drugs for minor species or minor uses? If so, what should those standards be?

**Comment:**

Yes, there should be different standards for manufacturing of drugs for minor species and for minor uses.

For example, nonfood minor species drug manufacturers should not be required to meet standards used for human drug or food animal drug manufacturing. Manufacturing of nonfood animal drugs should relate to minimum standards which provide consistency of product, animal safety and efficacy. Representative samples shown to be of effective concentrations for nonfood animal drug lots would be an adequate consistency standard. Standards for subcategories of nonfood minor animal species such as ornamental aquarium and garden pond fish should not include tissue residue testing, for example.

Each nonfood minor species industry should work with FDA to develop the standards required for that particular nonfood minor species.

**Question 11.** Should products be labeled to reflect the use of different manufacturing standards?

**Comment.**

Yes, products should be able to be labeled to reflect the use of different manufacturing standards. If reasonable drug approval and manufacturing standards can be agreed upon between FDA and the industry, there should be reference to modified standards on the label.

**Question 12.** Would a strategy similar to that used by the agency to facilitate drug approvals for some aquatic species be successful if extended to other minor species? That strategy includes coordination of Investigational New Animal Drug [INAD] information collected or generated by end users and it also includes a centrally-organized and FDA-operated field education program directed at end users as potential INAD sponsors. In which species/uses would such an approach work or not work? Why?

**Comment:**

The aquatic species, national NADA coordinator strategy has great merit and has been supported by APPMA since the program's inception. The program provides positive benefits for aquatic food minor animal species, which in turn provides data that can be used for drug approvals for aquatic nonfood minor species. For example, approved food animal drug labels should be extended to nonfood minor animal species use. However, the drug approval process designed within ADAA is not warranted when dealing with nonfood minor animal species, where low concentrations of drugs in small volumes are used.

D. Creating Incentives.

**Question 13.** Would economic incentives, such as tax breaks, grants, and periods of market or label exclusivity, encourage the pursuit of approvals or supplemental approvals for labeling modifications for minor species or minor uses? If so, what kind of incentives would be most effective?

Would different kinds of incentives be appropriate for different classes of new animal drugs, such as drugs for hobbyist-owned tropical fish as contrasted with production drugs for fish intended for human consumption?

What incentives would encourage sponsors to pursue approval of a drug for minor species or minor use, using data in public master files (PMF's)?

**Comment:**

The focal question should be the development of an affordable approval process for minor species and for minor uses. It would seem far more simple to provide an affordable process which allows sponsors to invest in a process of minor species drug approval.

Reduction of extensive and expensive approval procedures for nonfood minor species would be an excellent incentive. However, manufacturers of these drugs should also be provided with the same incentives given to manufacturers of human orphan drugs, e.g., tax breaks and grants.

Different strategies are certainly appropriate for food and nonfood minor animal species. FDA and minor species industry groups need to jointly determine the levels of risk involved and the approval process which is realistic. If this is done, the ability to market an approved drug is the incentive.

If the drug in question has a PMF, information should be available for

reference for the minor species approval process, avoiding duplication of effort and additional cost.

**Question 14.** Are there concerns about data in PMF's that make sponsors reluctant to rely on such data? What are these concerns? How could they be addressed?

**Comment:**

These issues should be addressed through a case-by-case review of the PMF in question. The PMF may not apply to the application of a minor species drug approval.

**Question 15.** If producer groups or other organizations were willing to conduct or otherwise fund studies to demonstrate safety and efficacy for new animal drug approvals for minor species or minor uses, would sponsors be willing to use the data from the studies to support approvals and new or revised labeling? If not, why not?

**Comment:**

The purpose for conducting the safety and efficacy studies would be to determine if the specific drug is suitable for use. If the testing protocol was approved by FDA prior to the testing and the test results were favorable, the data could be used by a sponsor as part of the submission packet for minor species or minor use approval, provided that the data was released by the group/organization conducting the study. In the case of ornamental aquarium and garden pond fish minor species, it may be appropriate to coordinate efforts with producer groups to determine priorities and needs, and to collaborate (as appropriate) on data collection toward the drug's approval.

**Question 16.** Should a program similar to the U.S. Department of Agriculture National Research Support Program #7 (NRSP-7), which currently funds studies for minor use therapeutic uses for food and fiber producing animals, be developed for wildlife and zoo animals and/or for production uses?

**Comment:**

If nonfood, non-fiber animals could be included in the existing program it might be advantageous to ornamental fish producers and hobbyists. We do not recommend that a separate, similar NRSP-7 program be developed to deal with nonfood, non-fiber animals.

**Question 17.** Should the NRSP-7 program be expanded to cover such uses?

**Comment:**

Yes, NRSP-7 should be expanded to cover such issues.

**Question 18.** Could and should philanthropic, public interest or other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for use in minor species or for minor uses? If so, how and by whom?

**Comment:**

Any organization with an interest in drug approval for a minor species are potential funding sources and should be encouraged to support research efforts.

**Question 19.** Are there mechanisms other than the new animal drug approval process and extra label uses of animal and human drugs under the AMDUCA that could enhance drug availability for minor species and for minor uses?

**Comment:**

Modification of the NADA process through ADAA appears to be the only vehicle for the creation of a new process which could expeditiously generate new drug approvals for minor species. Given the needed legal authority through ADAA, FDA modification of the existing drug approval process could provide therapeutic agent manufacturers of subclasses of nonfood minor species (such as ornamental aquarium and garden pond fish) the opportunity to obtain FDA approval for drugs.

AMDUCA is not currently a mechanism which provides fish hobbyists with approved therapeutic agents. Veterinary schools and a few practitioners who serve hobbyists could serve their clients through AMDUCA. At this time, only a few veterinarians nationwide offer services for ornamental fish species. The fish hobbyist has a history of obtaining fish health services from the aquarium store, from other knowledgeable hobbyists and clubs, or by using fish health texts. Veterinarians do not typically stock prepared fish drugs in their clinic pharmacies. Hopefully, well-labeled, approved drugs will provide veterinarians with the opportunity to refer clients to efficacious products that can be purchased over the counter at a pet store.

E. Extending Existing Legal Authority.

**Question 20.** Would legislation be desirable to extend the AMDUCA to permit extralabel use of: (1) Medicated feed, or (2) reproductive hormones and implants?

**Comment:**

The AMDUCA extension would have little impact on the hobby aquarium and garden pond fish since most owners do not rely on veterinarians for access to therapeutic agents. Drugs approved for use in nonfood ornamental aquarium and garden pond fish should be allowed to be combined in food as over-the-counter medicated feed to provide an additional delivery mechanism for treatment of diseased fish.

**Question 21.** What are the pros/cons of approval versus extralabel use under the AMDUCA?

**Comment:**

The fish hobbyist does not usually seek help from the veterinarian since this role has not been defined as a practice specialty by most veterinarians. Closer communication and coordination between pet stores and veterinarians would result in better diagnostic services and more effective treatment of ornamental aquarium and garden pond fish. It is important to develop a drug approval process that will result in the availability of FDA-approved fish therapeutic agents with accurate label information as over the counter drugs.

AMDUCA would provide legal access through extralabel use when an unapproved drug is not available for a minor use in nonfood fish species.

**Conclusion:**

Legislative and regulatory options are greatly needed that will facilitate the approval of new animal drugs intended for use in minor species and for minor uses, as contemplated in the ADAA, particularly for the nonfood minor animal species. Granting the FDA the flexibility to develop drug approval processes for nonfood minor species that use different standards than those applied to drugs for food animals will bring about a much needed increase in approvals for new animal drugs intended for these uses. This authority is greatly needed to address the scarcity of approved new animal drugs intended for nonfood minor species, particularly those that are maintained as pets, such as ornamental aquarium and garden pond fish.

APPMA urges the expeditious passage of legislative and regulatory options that will facilitate the approval of new animal drugs intended for use in minor species and minor uses, as contemplated in the ADAA, particularly for the nonfood minor animal species. The economics of the current NADA process effectively preclude FDA-approved drugs for treatment of minor nonfood species, since the standards are essentially the same for food animal species and nonfood species. This process is prohibitively expensive as applied to nonfood minor species because of the relatively small volume of sales for any one drug. Facilitating approvals for nonfood minor species will bring about a much needed increase in approvals of new animal drugs intended for these uses, which would be desirable to address the scarcity of approved new animal drugs intended for nonfood minor species.

APPMA is confident that a reasonable, effective and affordable drug approval process can be developed that will protect the public health, provide assurance of drug efficacy, and provide manufacturers of drugs with the ability to develop and market safe and effective treatments. This will in turn benefit American consumers by providing them with a wider range of safe and effective products for maintenance of the health, safety and comfort of their pets.

Manufacturers want to comply with a drug approval process that is designed to meet the needs of the public and the nonfood minor animals species such as ornamental garden pond and aquarium fish, while being affordable to the manufacturer and, ultimately, to the consumer.

Tracking Number

**3991802006****Recipient's Copy**

**1 From**  
 Date **9/5/97**  
 Sender's Name **Avis W. Effinger** Phone **(203) 5320000**  
 Dept./Floor/Suite/Room  
 Company **American Pet Products Manufacturers Association, Inc.**  
 Address **1255 Glenville Road**  
 City **Greenwich** State **CT** Zip **06831**

**2 Your Internal Billing Reference Information**

**3 To**  
 Recipient's Name **Dockets Management Branch (HEA-305)** Phone **301 594-1761**  
 Dept./Floor/Suite/Room  
 Company **Food & Drug Administration**  
 Address **12420 Parklawn Dr., Rm. 1-23**  
 City **Rockville** State **MD** Zip **20857**

**For HOLD at FedEx Location check here**  
 **Hold Weekday** (Not available with FedEx First Overnight)  
 **Hold Saturday** (Not available at all locations) (Not available with FedEx First Overnight or FedEx Standard Overnight)

**For Saturday Delivery check here**  
 (Extra Charge. Not available to all locations) (Not available with FedEx First Overnight or FedEx Standard Overnight)



**4a Express Package Service Packages under 150 lbs.** Delivery commitment may be later in some areas.  
 FedEx Priority Overnight (Next business morning)  **FedEx Standard Overnight** (Next business afternoon)  FedEx 2Day\* (Second business day)  
 **NEW FedEx First Overnight** (Earliest next business morning delivery to select locations) (Higher rates apply) \*FedEx Letter Rate not available. Minimum charge: One pound FedEx 2Day rate.

**4b Express Freight Service Packages over 150 lbs.** Delivery commitment may be later in some areas.  
 FedEx Overnight Freight (Next business-day service for any distance)  FedEx 2Day Freight (Second business day service for any distance)  FedEx Express Saver Freight (Up to 3 business-day service based upon distance)  
 (Call for delivery schedule. See back for detailed descriptions of freight products.)

**5 Packaging**  FedEx Letter (Declared value limit: \$500)  FedEx Pak  FedEx Box  FedEx Tube  Other Pkg.

**6 Special Handling**  
 Does this shipment contain dangerous goods?  No  Yes (As per attached Shipper's Declaration)  Yes (Shipper's Declaration not required)  
 Dry Ice (Dry Ice, 9, UN 1845 I) x kg 904 CA  Cargo Aircraft Only  
 (Dangerous Goods Shipper's Declaration not required)

**7 Payment**  Obtain Recipient FedEx Account No.  
 Bill to:  Sender (Account no. in (1) will be billed)  Recipient  Third Party  Credit Card  Cash/Check  
 (Enter FedEx account no. or Credit Card no. below)

Total Packages	Total Weight	Total Declared Value*	Total Charges
		\$ .00	\$

\*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.  
 Credit Card Auth.

**8 Release Signature**

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

**Questions?**  
**Call 1-800-Go-FedEx**  
 (1-800-463-3339)

**272**