fruits and vegetables. The voluntary guide is intended to assist growers, packers, and other operators in continuing to improve the safety of domestic and imported fresh produce.

ADDRESSES: Submit written requests for single copies of the guide to Lou Carson, Center for Food Safety and Applied Nutrition (HFS–32), 200 C St. SW., Washington, DC 20204, 202–260–8920. Send one self-addressed, self-adhesive label to assist that office in processing your request. Requests for copies of the guide should be identified with the docket number found in brackets in the heading of this document. A copy of the guide is available for public examination in the Dockets Management Branch, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. The guide is also accessible via the FDA home page on the World Wide Web (WWW) (http://www.fda.gov).

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–32), 200 C St. SW., Washington, DC 20204, 202–205–5916, FAX 202–260–9653, e-mail: ''jsaltsma@bangate.fda.gov'', or Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–2975, FAX 202–205–4422, e-mail: ''msmith1@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue within 1 year guidance on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA is coordinating the effort for DHHS.

Between November 17, 1997, and December 12, 1997, FDA and USDA held a series of public meetings to provide the details on a broad approach on how to minimize microbial contamination of produce through the control of water, manure, worker health and hygiene, field and facility sanitation, and transportation. A draft guidance document entitled ''Working Draft: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables'' was made available electronically on FDA's home page on the WWW (http://www.fda.gov) and at each public meeting.

In the **Federal Register** notice of April 13, 1998 (63 FR 18029), FDA announced the availability of a proposed guidance document entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.'' The proposed guidance document was also made available on FDA's home page and by mail to interested persons. The proposed guidance document responded to comments received on the working draft of the guidance document, as well as to comments received at the public meetings. FDA, in cooperation with USDA, held three public meetings between May 19, 1997, and May 27, 1998, to provide an overview of, and to seek additional public input on, the proposed guidance document. Transcripts of these meetings and all comments received on the proposed guide are on file in the Dockets Management Branch (address above) under the docket number appearing above and are accessible via the FDA home page on the WWW (http://www.fda.gov/ohrms/dockets).

In the April 13, 1998, notice, the agency asked for comments on the proposed guide and requested information about current agricultural practices, the cost of applying good agricultural and management practices, and ways to analyze costs and benefits to assess cost effective measures (63 FR 18029 at 18030). In response to that request, FDA received about 40 letters containing one or more comments in addition to many oral comments at the three public meetings held in May 1998. FDA has reviewed all of these comments, both oral and written, and has modified the proposed guide, as appropriate, in light of those comments. A number of comments were beyond the specific content of the guide. Therefore, the agency has prepared a written analysis of those comments, including those that addressed the agency's request for information about costs/benefits of agricultural practices, and has placed it in the docket (Docket No. 97N–0451). This analysis is available for review at the Dockets Management Branch (address above) or may be obtained via FDA's home page on the WWW (http://www.fda.gov/ohrms/dockets) under the docket number.

FDA is announcing the availability of the final guide. The guide responds to comments received on the proposed guidance document and represents FDA's and USDA's current thinking on strategies to minimize microbial hazards for fresh produce. The guide does not create or confer any rights for or on any person and does not operate to bind FDA, USDA, or the public. The guide is being distributed in accordance with the FDA's policy for Level 1 guidance documents as set out in the agency's Good Guidance Practices, published in the **Federal Register** of February 27, 1997 (62 FR 8961).

FDA believes that this guidance serves as an important step in addressing the risks of foodborne illness associated with fresh produce. There are, at this time, limited data available on current agricultural practices. To gather better data and provide a foundation for the agency's future evaluation of the impact of the guidance, FDA is working with USDA's National Agricultural Statistics Service (NASS) to design and conduct a survey of current domestic agricultural production and packing practices for fresh produce. The objective of the survey is to document the prevalence and variety of practices currently used in the production of fresh fruits and vegetables in the United States. The survey will focus on practices that are addressed in the guide, including practices related to agricultural water quality, manure management, packinghouse sanitation, and worker hygiene. The survey development process has included an industry advisory group to help ensure the effectiveness of the survey. NASS plans to conduct a pilot test survey of two States and approximately 30 commodities in fiscal year (FY) 1999 and, depending on resources, to conduct a nationwide survey in FY 2000.

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29022 Filed 10–26–98; 2:39 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0217]

Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor

Species and Minor Uses.'' The report contains proposals for legislative, regulatory, and policy changes to the approval process for new animal drugs intended for use in minor species and for minor uses in major species (minor use drugs). This report is the agency's response to the requirement of the Animal Drug Availability Act of 1996 (the ADAA) that the Secretary of Health and Human Services (the Secretary) consider and announce proposals to facilitate approvals for minor use drugs. Implementation of these proposals should result in an increase in the number of approved new animal drugs for use in minor species and for minor uses.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written comments on the report to Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will also accept e-mail comments. They should be labeled as comments, be identified with the docket number found in brackets in the heading of this document, and be addressed to ''jbutlerl@bangate.fda.gov''. The agency will make paper copies of the comments and will place them in the public docket along with the comments submitted in writing.

Submit written requests for single copies of ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses'' to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Enclose one self-addressed adhesive label to assist that office in processing your requests. Copies of this report are also posted on the Center for Veterinary Medicine (CVM) Internet home page at ''http://www.fda.gov/cvm''.

FOR FURTHER INFORMATION CONTACT:

For questions about section 2(f) of the ADAA: George A. (Bert) Mitchell, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5587, FAX 301–594–1807, e-mail ''gmitchel@bangate.fda.gov'', or

For further information about the changes proposed in the report to the approval process: Linda Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614, FAX 301–594–2297, e-mail ''lwilmot@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background.

On October 9, 1996, the President signed the ADAA (Pub. L. 104–250) into law. Enactment of the ADAA reflected Congress' concerns about the lack of availability of approved new animal drugs. Among other things, the legislation recognized particular problems relating to the availability of approved new animal drugs for minor uses in major species and for use in minor species (minor use drugs).

Section 2(f) of the ADAA directs the Secretary to consider legislative and regulatory options for facilitating approval under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) of new animal drugs intended for use in minor species or for minor uses. The ADAA statute further requires the Secretary to announce within 18 months after the date of enactment proposals for legislative or regulatory change to the approval process for new animal drugs intended for use in minor species or for minor uses. Publication of the notice announcing the availability of ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses, ADAA Minor Use/Minor Species Working Group'' fulfills that statutory obligation.

The authority of the Secretary regarding new animal drug approvals is delegated to the Commissioner of Food and Drugs by 21 CFR 5.10, and that authority is redelegated to the Director and Deputy Director of CVM in 21 CFR 5.83. In order to respond to the ADAA mandate, CVM established a working group of scientific, legal, and policy experts in animal drug approval and minor species issues to explore possible solutions to the problem and to draft a report with proposals. The working group, recognizing that public input was critical to the development of proposals that would most broadly and effectively facilitate approvals, solicited comments from the public through a **Federal Register** document entitled ''Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and Minor Uses'' (62 FR 33781, June 23, 1997).

In addition, on December 19, 1997, CVM posted on its Internet home page a discussion draft entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses.'' The discussion draft, which was identified as a ''working document,'' included discussions of several options for possible change. CVM encouraged the public to comment on the concepts in the working document and to express any related concerns, and asked for comments on a number of specific questions that focused on particular issues.

CVM received 110 comments in response to the two documents. Among those commenting were minor-species producer groups, exotic-animal (e.g., guinea pigs, ornamental fish) breeders, pharmaceutical companies, veterinarians, zoological organizations, the American Veterinary Medical Association, trade associations, pet shop owners, university faculty, and members of other Federal and State regulatory agencies. The comments were extensive, indicating a high level of interest in the draft proposals. All the comments were reviewed and many have been incorporated into the recommendations. The comments are on file in Docket No. 97N–0217 and may be viewed in the Dockets Management Branch (address above) and on FDA's home page at ''http://www.fda.gov''.

II. The Report

While the proposals in this report represent FDA's best thinking for facilitating the approval of animal drugs for minor uses and for use in minor species, the report is not intended to represent formal administration position in support of any of the proposals. FDA hopes that the announcement of these proposals will engender further debate on these issues and stimulate the interest of drug sponsors, manufacturers, and individuals who care for and raise animals.

The report describes a range of legislative and regulatory proposals intended to facilitate minor use and minor species drug approvals and to otherwise increase the legal availability of drugs for minor uses and minor species. The proposals are as follows:

1. Creation by Statute of a ''Minor Use Animal Drug'' Program
2. Enhancement of Existing Programs for Data Development
3. Conditional Drug Approval for Minor Uses With No Human Food Safety Concern
4. An Alternate Process to Provide for Legal Marketing of New Animal Drugs for Minor Species With No Human Food Safety Concern
5. Other Legislative Options
6. Other Changes in Regulation or Policy

FDA has presented a broad array of options in response to the congressional charge to propose changes that would facilitate the approval of new animal drugs for minor species or minor uses. It is the agency's perception that neither the current animal drug approval process nor any other single approval process can adequately address the

enormous diversity of minor species for which animal drugs are needed. Each proposal has merit with respect to certain minor species or minor uses.

Many of the proposals require legislative change. Congress recognized the possibility that statutory changes might be needed in its charge at Section 2(f) of the ADAA. On close examination, the existing statutes simply fail to provide adequate options for FDA and sponsors to fully serve the minor species and minor use needs of the literally hundreds of animal species that people care for. To achieve the goal of increasing the availability of safe and effective drugs for minor species and minor uses, FDA concludes that Federal statutes must be amended.

FDA is willing to work with Congress and other concerned parties to further characterize any proposed statutory changes and to assist as requested and as appropriate in their enactment. If the act is amended as a result of these proposals, the agency will focus its efforts on issuing any necessary regulations through notice and comment rulemaking or otherwise implementing the statutory changes as directed. Increasing the availability of drugs for minor species and minor uses increases protection of public and animal health and is a significant issue for FDA.

III. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this report. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–28903 Filed 10–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R–263]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because we have determined that the information collection instrument in question is necessary for our contractor and subcontractor to carry out site visits of suppliers of durable medical equipment, prosthetics, orthotics, or supplies who wish to bill the Medicare program. These site visits are being carried out in accordance with an announcement by the President on January 24, 1998, that all such suppliers would receive site visits. The visits commenced on June 1, 1998, and the instrument was developed after we had gained some experience with the visits. We are requesting emergency clearance to maximize the benefits to be gained from this effort and to avoid discontinuity in this important fraud prevention mechanism.

HCFA is requesting OMB review and approval of this collection within eleven working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within ten working days. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New Collection.

Title of Information Collection: On-Site Inspection for Durable Medical Equipment (DME). Supplier Location and Supporting Regulations in 42 CFR 424.57.

Form No.: HCFA-R–263 (OMB# 0938–NEW).

Use: To identify and implement measures to prevent fraud and abuse in the Medicare program. Controlling the entry of suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) to Medicare has been identified as one of the most effective ways to prevent fraud and abuse. To meet this challenge, HCFA is moving forward with a plan to improve the quality of the process for enrolling and reenrolling DMEPOS suppliers into the Medicare program by enhancing procedures for verifying supplier information collected on the Form HCFA 855S (DMEPOS Supplier Enrollment Application, OMB Approval No. 0938–0685). This form will be used to complete information on DMEPOS suppliers' compliance with regulations found in 42 CFR 424.57.

Frequency: On occasion.

Affected Public: Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government.

Number of Respondents: 40,000.

Total Annual Responses: 40,000.

Total Annual Hours: 20,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees