for overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Detrol (U.S. Patent No. 5,382,600) from Pharmacia & Upjohn Atiebolag, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Detrol represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Detrol is 1,267 days. Of this time, 901 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 7, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 7, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* March 25, 1997. The applicant claims March 24, 1997, as the date the new drug application (NDA) for Detrol (NDA 20–771) was initially submitted. However, FDA records indicate that NDA 20–771 was submitted on March 25, 1997.

3. *The date the application was approved*: March 25, 1998. FDA has verified the applicant's claim that NDA 20–771 was approved on March 25, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 64 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by September 10, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 7, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–17105 Filed 7–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Draft Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues'' (the draft guidance). The draft guidance presents FDA's policy for implementing the channels of trade provision for the pesticide chemical vinclozolin in the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996. The draft guidance is intended to assist firms in understanding FDA's planned approach to the enforcement of this provision of the FQPA with regard to residues of vinclozolin in food.

DATES: Submit written comments concerning on the draft guidance by September 10, 2001, to ensure their adequate consideration of the comments in the preparation of a revised guidance, if warranted. However, you may submit comments at any time.

ADDRESSES: Submit written comments concerning the draft guidance and the collection of information provisions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues'' to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681, FAX 202–205–4422, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On August 3, 1996, the FQPA was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA, established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. In accordance with the FQPA, the Environmental Protection Agency (EPA), is responsible for regulating the use of pesticides (under the FIFRA) and establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FFDCA). EPA, in accordance with the FQPA, is in the process of reassessing the pesticide tolerances and exemptions that were in effect when the FQPA was signed into law. When EPA determines that a pesticide's tolerance level does not meet the safety standard under section 408 of the act (21 U.S.C. 346a), the registration for the pesticide may be canceled under the FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the FFDCA (21 U.S.C. 346a(l)(2)), when the registration for a pesticide is canceled or

modified due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture (USDA) has responsibility for monitoring residue levels and enforcing pesticide tolerances in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. FDA would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an ''adulterated'' food. However, the channels of trade provision of the FQPA address the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the FFDCA) states the following:

PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that-

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under the tolerance, exemption, food additive regulation, or other sanction then in effect under this Act; unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

For reasons explained by EPA in its proposed rule on pesticide tolerance revocations published elsewhere in this issue of the **Federal Register**, EPA is proposing to revoke the pesticide tolerances for vinclozolin on bell peppers andcucumbers[1], and also is proposing to revoke the pesticide tolerances for vinclozolin on strawberries and stonefruit as quickly as possible after consideration of comments.

FDA anticipates that some processed strawberries and stonefruit bearing vinclozolin residues resulting from lawful domestic application of this pesticide will remain in the channels of trade after the revocation of the applicable tolerance. In addition, FDA anticipates that some bell peppers and cucumbers, both fresh and processed, that were legally imported bearing residues of vinclozolin will be in the channels of trade after the revocation of the applicable tolerance. If FDA encounters processed strawberries, processed stonefruit, fresh or processed bell peppers, or fresh or processed cucumbers bearing a residue of vinclozolin, it intends to address the situation in accordance with this draft guidance. FDA has developed this draft guidance to set forth its policy for how FDA plans to approach its enforcement of the channels of trade provision with respect to the pesticide chemical vinclozolin.

With this document, FDA is announcing the availability of the draft guidance. The draft guidance represents FDA's current thinking on its planned enforcement approach to the channels of trade provision and how such provision relates to FDA-regulated products with vinclozolin residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The draft guidance is being distributed for comment purposes, in accordance with the FDA's final rule on administrative practices and procedures for good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues

Description: Under the pesticide tolerance reassessment process that EPA wasmandated to carry out under the FQPA, EPA has proposed to revoke the tolerances for the pesticide chemical vinclozolin on several food commodities. The FQPA includes a provision in section 408(l)(5) of the FFDCA, referred to as the ''channels of trade provision,'' that addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain vinclozolin residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, will be able to demonstrate that such food was packed or processed during the acceptable timeframes cited in the draft guidance, by providing appropriate documentation to the agency as discussed in the draft guidance. FDA is not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered

[1]Vinclozolin is not registered for use on bell peppers and cucumbers in the United States. The tolerances for vinclozolin on bell peppers and cucumbers provide the importation of these commodities with vinclozolin residues.

unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation which FDA anticipates will serve this purpose consists of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of vinclozolin after the tolerances for this pesticide chemical have been revoked.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
307	1	307	3	921

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Recordkeeper	Total Hours
31	1	31	16	496

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes might be found to contain vinclozolin residues. The estimated annual reporting burden was determined using the total number of samples historically tested for vinclozolin and the number of samples that historically contained vinclozolin residues. These numbers established a rate of samples expected to contain vinclozolin residues. This rate, when applied to the number of potentially affected establishments, was used to calculate the number of expected respondents.

When determining the estimated annual recordkeeping burden, FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms which may not currently be maintaining this documentation to develop and maintain (or maintain access to) documentation such as batch records, inventory records, sales records, and distribution records.

III. Comments

Interested persons should submit to the Dockets Management Branch (address above) written comments regarding the draft guidance by September 10, 2001, to ensure adequate consideration of the comments of the comments in the preparation of a revised guidance, if warranted. However, interested persons may submit written comments at any time. 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. Submit to the Dockets Management Branch written comments concerning this collection of information by September 10, 2001. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance is available on the Internet at http://www.fda.gov.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17047 Filed 7–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–372]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.181 and 441.300–.305; *Form No.:* HCFA–372 (OMB# 0938–0272); *Use:* States request waivers in order for beneficiaries to have the option of receiving hospital services in their homes. States with an approved waiver under section 1915(c) of the Act are required to submit the HCFA–372 or HCFA–372(S) annually in order for HCFA to: (1) Verify that State assurances regarding waiver cost-neutrality are met, and (2) determine the waiver's impact on the type, amount and cost of services provided under the State plan and health and welfare of recipients; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 243; *Total Annual Hours:* 18,225.