tolerances for the pesticide chemical vinclozolin on several food commodities. The FQPA includes a provision in section 408(l)(5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a(l)(5)), 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under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.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found to contain vinclozolin residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, will be able to demonstrate that such food was packed or processed during the acceptable timeframes cited in the draft guidance, by providing appropriate documentation to the agency as discussed in the draft guidance.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 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.

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handle food products that may contain residues of vinclozolin after the tolerances for this pesticide chemical have been revoked.

In the **Federal Register** of July 10, 2001 (66 FR 35990), the agency requested comments on the proposed collection of information. No comments were received.

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 Recordkeeping	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.

Dated: October 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–26651 Filed 10–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committees and Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on its advisory committees and panels in the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, and the Center for Food Safety and Applied Nutrition. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2002.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations should be received approximately 6 months before the vacancy dates listed in this notice.

ADDRESSES: All nominations with curricula vitae or resume (which should include nominee's office address, telephone number, and e-mail address) should be submitted to Maureen Hess (address below).

FOR FURTHER INFORMATION CONTACT: Maureen Hess, Office of Consumer Affairs (HFE–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5006, e-mail: MHess@oc.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and nonvoting consumer representatives of the following nine advisory committees and panels for vacancies listed below.

Center for Devices and Radiological Health

1. *Clinical Chemistry and Clinical Toxicology Devices Panel*: One vacancy occurring February 28, 2002.
2. *Circulatory System Devices Panel*: One vacancy occurring June 30, 2002.
3. *Gastroenterology and Urology Devices Panel*: One vacancy occurring December 31, 2002.
4. *General and Hospital Personal Use Devices Panel*: One vacancy occurring December 31, 2002.

Center for Drug Evaluation and Research

1. *Anesthetic and Life Support Drugs Advisory Committee*: One vacancy occurring March 31, 2002.
2. *Medical Imaging Drugs Advisory Committee*: One vacancy occurring June 30, 2002.
3. *Psychopharmacologic Drugs Advisory Committee*: One vacancy occurring June 30, 2002.
4. *Advisory Committee for Pharmaceutical Science*: one vacancy occurring October 31, 2002.

Center for Food Safety and Applied Nutrition

1. *Food Advisory Committee*: Five vacancies occurring June 30, 2002.

I. Criteria for Members

Persons nominated for membership on the committees as a consumer representative shall have demonstrated ties to consumer and community-based organizations and be able to analyze data, understand research design, discuss benefits and risks, and evaluate the safety and effectiveness of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee, serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations, and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

II. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include use of a list of organizations representing the public interest and consumer advocacy groups. The list of organizations has the responsibility for recommending candidates for the agency's selection.

III. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–26572 Filed 10–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 30, 2001, from 9:45 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a conductive keratoplasty (CK) refractive surgical device for the reduction of previously untreated spherical hyperopia in patients 40 years of age or greater, who have 0.75 diopter (D) to 3.25 D of cycloplegic spherical hyperopia, with less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 D to 3.00 D, and no more than 0.50 D difference between preoperative manifest refraction spherical equivalent (MRSE) and cycloplegic refraction spherical equivalent (CRSE) which shows some regression of the initial effect over time. Background information, including the agenda and questions for the committee, will be available to the public on November 29, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 16, 2001. Formal oral presentations from the public will be scheduled between approximately 9:50 a.m. and 10:20 a.m. Near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Those desiring to make formal oral presentations should notify the contact person before November 16, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–26574 Filed 10–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.