believe that recalling firms are usually aware of the significance of the defect in a recalled product and know the likely FDA classification. This may be based on the firm's own health hazard evaluation, by precedent recalls and information published on FDA's Web sites, and/or by verbal communication with FDA district office recall coordinators. The latter is especially true regarding the classification of serious to potentially life-threatening hazard-to-health recall actions (class I). In such situations, the delivery of a classification letter usually follows extensive communications between recalling firms and FDA in which classification, recall strategy, and press releases are immediately discussed.

We have accepted the commenter's estimate of the time expended to conduct recalls and have used those figures, coupled with revised recall numbers, to develop what we believe to be a more realistic estimate of the time expended by FDA-regulated industry to develop and report recall information requested by FDA.

FDA agrees with the comment to have a process whereby reports and any other necessary information can be submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. Certainly there is no reason not to use e-mail or facsimile communications in most recall situations; however, FDA would maintain the prerogative for investigational visits and other in-person communications where the agency considers it appropriate. In fact, FDA is currently working toward providing ''industry guidance'' online which will provide a format for industry responses to recall situations.

At the present time, the names and telephone numbers of FDA's district office recall coordinators may be found on the Internet at http://www.fda.gov/ora/inspect—ref/iom/iomoradir—monitors.html#RECALL. Unfortunately, this provides information from FDA's latest published location directory and is not always current. We will see that this list is updated if it is possible to do so. Additionally, changes to the FDA Web site's recall information and reporting systems which are currently under development, will maintain an easy to locate, user-friendly recall section that will include a current listing of all district coordinators that will include names, telephone and facsimile numbers, mail, and e-mail addresses.

At this time, we will refer to the Center for Food Safety and Applied Nutrition your suggestion to allow processing authorities to authorize reconditioning/destruction of thermally processed low acid and acidified foods in hermetically sealed containers and for the recalling firm to then submit a summary of the disposition action to FDA.

As a result of the comment received, the following is a revised summary of the estimated annual burden hours for manufacturers, processors, and distributors to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency perResponse	Total Annual Responses	Hours per Response	Total Hours
7.42	1,855	1	1,855	15	27,825
7.26 and 7.49	1,855	1	1,855	20	37,100
7.53	1,855	4	7,420	10	74,200
7.55(b)	1,855	1	1,855	10	18,550
Total					157,675

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

Dated: August 13, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20842 Filed 8–16–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs 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: Anti-Infective Drugs 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 September 13, 2001, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations on the proposed approach for selection of delta in noninferiority (equivalence) clinical trials. The impact of this approach on studies of anti-infective drug products will be considered, with a focus on acute exacerbation of chronic bronchitis and hospital-acquired pneumonia.

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 September 4, 2001. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 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: August 10, 2001.

Bonnie H. Malkin,

Acting Senior Associate Commissioner.

[FR Doc. 01–20801 Filed 8–16–01; 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 September 21, 2001, from 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, 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 soft contact lenses for the correction of refractive ametropia (myopia or hyperopia) in phakic or aphakic persons with nondiseased eyes exhibiting astigmatism of 2.00 diopters (D) or less that does not interfere with visual acuity. The lenses may be prescribed for daily wear or extended wear for 1 to 30 days between removals for cleaning and disinfection or for disposal of the lens, as recommended by the eye care professional. The lens may be prescribed in spherical powers ranging from +20.00 D to -20.00 D. The committee will also discuss, make recommendations, and vote on a conductive keratoplasty refractive surgical device for the reduction of previously untreated spherical hyperopia in patients 40 years of age or greater, who have 0.75 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 and cycloplegic refraction spherical equivalent 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 September 20, 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 September 14, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. Near the end of the committee deliberations on each 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 September 7, 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: August 10, 2001.

Bonnie H. Malkin,

Acting Senior Associate Commissioner.

[FR Doc. 01–20802 Filed 8–16–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–33]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

DATES: August 17, 2001.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless.

Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: August 9, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 01–20440 Filed 8–16–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Final Environmental Impact Statement for the Proposed Issuance of an Incidental Take Permit for the Metro Air Park Habitat Conservation Plan, Sacramento County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: This notice advises the public of the availability of the Final Environmental Impact Statement on the application to incidentally take 2 federally listed species and 12 currently unlisted species should any of them become listed under the Endangered Species Act of 1973, as amended (Act), during the life of the permit. The Metro Air Park Property Owners Association (Association) has applied to the Fish and Wildlife Service (Service) for a 50-year incidental take permit pursuant to