Respondent	No. of respondents	No. of responses respondents	Avg. burden response (in hrs.)	Total burden (in hrs.)
Total				18

Dated: January 14, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–1340 Filed 1–17–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Dental Products Panel of the Medical Devices Advisory Committee

Date, time, and place. February 12, 1997, 9 a.m., Gaithersburg Marriott Washingtonian Center, Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–590–0044 and reference the FDA Dental Products Panel meeting block. Reservations may be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Christie Wyatt, KRA Corp., 301–495–1591, ext. 267. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing for the reclassification of over-the-counter (OTC) denture cushions or pads, 9 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 11:30 a.m.; open public hearing for the reclassification of temporary mandibular condyle implant prostheses, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5:30 p.m.; Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Dental Products Panel, code 12518. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 5, 1997, 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 required to make their comments.

Open committee discussion. The committee will discuss two petitions for the reclassification of OTC denture cushions or pads that are prefabricated or noncustom made disposable devices intended to improve the fit of loose or uncomfortable dentures. (This does not include OTC denture cushions or pads made of wax-impregnated cotton cloth that are to be applied to the base or inner surface of a denture and are to be discarded following 1 day's use; this device is presently class I). The committee will also discuss a petition for the reclassification of mandibular condyle implant prostheses for temporary use in the treatment of patients following tumor resection.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the

contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 13, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–1337 Filed 1–17–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

National Practitioner Data Bank; Change in User Fee

The Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS), is announcing the elimination of the discount fee charged to entities authorized to request information from the National Practitioner Data Bank (Data Bank) for queries which meet all requirements for fully automated processing.

The current fee structure was announced in the Federal Register on February 8, 1996 (61 FR 4788). The user fee is $3.00 less $1.00 discount per name per query fee for queries submitted via telecommunications network and paid via an electronic funds transfer or credit card, with query response sent via the telecommunications network. Six dollars is charged for queries submitted electronically on a diskette to pay for the extra handling and mailing costs for these queries. An additional $4.00 is charged for all queries which are paid for by check or money order rather than by electronic funds transfer or credit card to cover the cost of debt management.

The Data Bank is authorized by the Health Care Quality Improvement Act of 1986 (the Act), title IV of Public Law 99–660, as amended (42 U.S.C. 11101 *et seq.*). Section 427(b)(4) of the Act authorizes the establishment of fees for the costs of processing requests for disclosure and of providing such information.

Final regulations at 45 CFR part 60 set forth the criteria and procedures for information to be reported to and disclosed by the Data Bank. Section 60.3 of these regulations defines the terms used in this announcement.

In determining any changes in the amount of the user fee, the Department uses the criteria set forth in §60.12 (b) of the regulations, as well as allowable costs pursuant to the DHHS Appropriations Act of 1997, P.L. 104–208, enacted September 30, 1996. This Act requires that the Department recover the full costs of operating the Data Bank through user fees. Paragraph (b) of the regulations states:

''The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.''

Based on analysis of the comparative costs of the various methods for filing and paying for queries, the Department is eliminating the $1.00 discount fee for users who: (1) query and receive responses via the telecommunications network, and (2) pay query fees by credit card, electronic funds transfer or such other electronic transfer options as may be offered in the future.

Despite the elimination of the discount, electronic querying (telecom network) and electronic payment continue to be the most cost-effective methods for requesting information from the Data Bank. Consequently, the fee for querying the Data Bank by diskette with electronic payment continues to be $6.00. The new fee for electronic queries (telecom network) with electronic payment will be $3.00. This change is effective February 20, 1997.

When a query is for information on one or more physicians, dentists, or other health care practitioners, the appropriate total fee will be $3.00 (plus a $3.00 and/or a $4.00 surcharge for submission and payment as described above) multiplied by the number of individuals about whom information is being requested. All other fees remain the same. For examples, see the table below.

The Department will review the user fee periodically, and will revise it as necessary. Any changes in the fee and their effective date will be announced in the Federal Register.

Query method	Fee per name in query, by method of payment	Examples
Electronic query (Telecom network) with electronic payment.	$3.00 (if paid electronically via credit card or other electronic means and response received electronically).[1].	10 names in query. 10x$3 = $30.00.
Electronic query (Diskette) with electronic payment.	$6.00 (if paid electronically via credit card or other electronic means and response received on paper) ($3.00 fee plus $3.00 surcharge).	10 names in query. 10x$6 = $60.00.
Electronic query (Telecom network) with non-electronic payment.	$7.00 (if not paid via credit card or other electronic means) ($3.00 fee plus $4.00 surcharge).	10 names in query. 10x$7 = $70.00.