

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4628) has been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposes to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of 1-octene as an optional monomer in the preparation of polymers for use as resins in adhesives for articles used in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 23, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-26644 Filed 10-5-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance 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: National Mammography Quality Assurance 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 2, 1998, 9 a.m. to 6 p.m., and November 3, 1998, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Charles A. Finder, Center for Devices and Radiological

Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 2, 1998, the committee will discuss the compliance draft guidance entitled "The Mammography Quality Standards Act Final Regulations." Single copies of the draft guidance document are available to the public by calling 1-800-899-0381 or 301-827-0111, and requesting Fact-on-Demand number 1259, or on the Internet using the World Wide Web (WWW) (<http://www.fda.gov/cdrh/dmgrp.html>). On November 3, 1998, the committee will receive updates on the issues of States as certifying bodies under the Mammography Quality Standards Act (the MQSA), congressional reauthorization of the MQSA, and Voluntary Stereotactic Accreditation Programs.

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 October 5, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on November 2, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, 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: September 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirements for opportunity for public comment on proposed data collection projects (section 3506(c) (2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms, OMB No. 0915-0126: Extension

The National Practitioner Data Bank (Data Bank) was established through Title IV of Pub. L. 99-660, the Health Care Quality Improvement Act of 1986, as amended. Final Regulations governing the Data Bank are codified at 45 CFR Part 60. Responsibility for Data Bank implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration, U.S. Department of Health and Human Services (DHHS). The Data Bank began operation on September 1, 1990.

The intent of Title IV of Pub. L. 99-660 is to improve the quality of health care by encouraging hospitals, State licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior;

and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure of the practitioners' previous damaging or incompetent performance.

The Data Bank acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information on medical malpractice payments, adverse licensure actions, adverse clinical

privileging actions, and adverse professional society actions is collected from, and disseminated to eligible entities. It is intended that Data Bank information should be considered with other relevant information in evaluating a practitioner's credentials.

This request is for an extension of reporting and querying forms previously approved in February 1996. The reporting forms and the request for information forms (query forms) may be accessed, completed, and submitted to

the Data Bank electronically through the use of a program designated QPRAC 4 which is provided by the DHHS. The DHHS has developed a separate query form for practitioners making self-queries. This request also includes several administrative forms which have been developed since the last clearance.

The following estimates of burden are based on actual Data Bank operational experience:

Type of Activity—45 CFR 60.0	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Reporting:				
Reports Correcting Errors and Omissions—60.6(a)	1,600	1.06	25	424
Reports of Revision to Actions Previously Reported—60.6(b)	390	1.04	.75	304
Report of Medical Malpractice Payments—60.7(b)	525	27.3285	.75	14,347
Reports of Adverse Actions by State Medical and Dental Boards—60.8(b)	125	32.56	.75	3,053
Reports of Adverse Action Regarding Clinical Privileges and Professional Society Memberships—60.9(a)	3975	1.03	.75	753
Entity Hearings:				
Requests for Hearing by Entities—60.9(c)	11	1	8.0	8
Requests for Information Disclosure (Query):				
Queries by Hospitals for Practitioner Applications—60.10(a)(1)	6,000	40	.083	19,920
Queries by Hospitals—Two Year Cycle—60.10(a)(2)	6,000	160	.083	79,680
Queries by Hospitals—Peer Review—60.11(a)(1)	2			
Queries by Practitioners (Self-Query)—60.11(a)(2)	60,000	1	.50	30,000
Queries by Licensure Boards—60.11(a)(3)	125	120	.083	1,245
Queries by Non-Hospital Health Care Entities—60.11(a)(4)	3,250	690	.083	186,128
Queries by Plaintiff's Attorneys—60.11(a)(5)	(³) 1	1	.30	.5
Queries by Non-Hospital Health Care Entities—Peer Review—60.11(a)(6)	(³)			
Requests by Researchers for Aggregate Information—60.11(a)(7)	100	1	.50	50
Disputes:				
Practitioner Places a Dispute in His/Her Data Bank Report—60.14(b)	1,200	1	.5	600
Practitioner Places a Statement in His/Her Data Bank Report—60.14(b)	1,350	1	1.0	1,350
Practitioner Requests Review of the Disputed Report by The Secretary DHHS—60.14(b)	135	1	8.0	1,080

ADMINISTRATIVE FORMS USED IN OPERATING THE NATIONAL PRACTITIONER DATA BANK

Entity Registration Form	150	1	1.0	150
Entity Registration Update Form	100	1	.25	25
Authorized Agent Designation Form	25	1	.25	6.25
Authorized Agent Designation Update	5	1	.083	.42
Account Discrepancy Report	200	1	.25	50
Electronic Transfer of Funds Authorization	25	1	.25	6.25
Entity Reactivation	50	1	.25	12.5
Total				339,193

¹ There have been no hearing requests from reporting entities since the opening of the Data Bank.

² We are unable to distinguish between these and other types of queries made by hospitals and other health care entities.

³ There have been approximately 12 attorney requests since the opening of the Data Bank; of these, one has been granted.

⁴ 5 minutes.

Send comments to Susan Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-1129; Written

comments should be received within 60 days of this notice.

Dated: September 30, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

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