

Dated: July 22, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98-20076 Filed 7-27-98; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0567]

The Dow Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of copolymers of ethylene and octene-1 as articles or components of articles contacting food.

DATES: Written comments on the petitioner's environmental assessment by August 27, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

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 8B4601) has been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposes to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to expand the safe use of ethylene-octene-1 copolymers as articles or components of articles contacting food by lowering the required level of polymer units derived from ethylene to not less than 50 weight percent.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for

public review and comment. Interested persons may, on or before August 27, 1998, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-20038 Filed 7-27-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, called the "National Provider System (NPS)," HHS/HCFA/OIS No. 09-70-0008. We have provided background information about the proposed system in the "Supplementary Information" section below. Both institutional (e.g., hospitals, skilled nursing facilities) and individually identifiable (e.g., physicians and other practitioners) providers are included in the NPS database. The institutional providers' data are covered by section 1106 of the Social Security Act and the Freedom of Information Act, while the individually identifiable providers' data are also covered by the Privacy Act of 1974. Although the Privacy Act requires

only that the "routine uses" portion of the system be published for comment, HCFA invites comments on all portions of this notice. See "Effective Dates" for comment period.

EFFECTIVE DATES: HCFA filed a new system report with the Chairman of the Committee on Government Reform and Oversight of the House of Representatives, the Chairman of the Committee on Governmental Affairs of the Senate, and the Acting Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on July 8, 1998. The new system of records, including routine uses, will become effective 40 days from the date submitted to OMB and the Congress, unless HCFA receives comments which require alteration to this notice. HCFA will also consider revisions to this notice based upon comments received on the National Provider Identifier (NPI) notice of proposed rulemaking (FR/Vol. 63, No. 88/May 7, 1998). The NPS will not become operational until sometime after the NPI final rule is published and the system is in full compliance with the requirements of the final rule.

ADDRESSES: The public should address comments to the HCFA Privacy Act Officer, Division of Freedom of Information & Privacy, Office of Information Services, Health Care Financing Administration, 7500 Security Boulevard, C2-01-11, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location by appointment during regular business hours, Monday through Friday 9 a.m.—3 p.m. Eastern Time Zone.

FOR FURTHER INFORMATION CONTACT: Patricia Peyton, Office of Information Services, Health Care Financing Administration, 7500 Security Boulevard, N3-09-16, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-1812.

SUPPLEMENTARY INFORMATION: This system will allow better administration of all health care programs. Currently, there is no standard health care provider identifier in use in the health care industry. Health care providers are assigned multiple identifiers by the health plans in which they participate; such assignments are made routinely and independently of each other. The identifiers are frequently not standardized within a single health plan or across plans. A single health care provider may have different identification numbers for each health program, and often multiple billing numbers issued within the same program.

Nonstandard enumeration of health care providers significantly complicates health care providers' claims submission processes. It also contributes to the unintentional issuance of the same identification number to different health care providers.

Most health plans have to be able to coordinate benefits with other health plans to ensure appropriate payment. The lack of a single, unique identifier for each health care provider within each health plan and across health plans, based on the same core data, makes exchanging data both expensive and difficult.

These factors, which indicate the complexities of exchanging information on health care providers within and among organizations, result in increasing numbers of claims-related problems and increasing costs of data processing. The need for a standard health care provider identifier becomes more and more evident as we become more dependent on data automation and proceed in planning for health care in the future.

In addition to overcoming communication and coordination difficulties, use of a standard, unique health care provider identifier would enhance our ability to eliminate fraud and abuse in health care programs.

This system will issue the standard health care provider identifiers—called National Provider Identifiers (NPIs)—which will be used by Medicare, Medicaid, other Federal programs named as health plans, non-Government health plans, health care providers, and health care clearinghouses.

This initiative was mandated by the administrative simplification provisions of Pub. L. 104-191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA mandates the adoption of a standard health care provider identifier and its assignment to every health care provider that transacts electronically any of the transactions specified in that law. Creation of a standard health care provider identifier and its assignment to Medicare and Medicaid providers also supports HCFA's Strategic Plan goal of data standardization.

It is important to clarify that NPS responsibilities are limited to unique health care provider identification, enumeration of those health care providers, and updating the health care provider enumeration data. Responsibility for determining whether a provider is qualified for any particular program remains the responsibility of that program. Furthermore, the creation of a national health care provider identifier should not alter the current

relationship between health care providers and health plans in any fundamental way; health care providers will still be governed by each health plan's rules for program enrollment, credentialing and claims submission. The NPS will provide the means to uniquely identify and enumerate a health care provider at the national level.

The Department of Health and Human Services is proposing, in a notice of proposed rulemaking, that the information needed to enumerate health care providers that participate in Federal health plans (e.g., Medicare, Tricare/CHAMPUS) and Medicaid be obtained from the pre-existing health care provider enrollment databases of those plans. Approximately 85 percent of health care providers requiring NPIs exist in those databases. Enumerating information about the remaining health care providers requiring NPIs will be obtained from an application form. Information in the Federal health plan and Medicaid enrollment databases will be validated and reformatted into the NPS Standard Record Format so it can be loaded into the National Provider System.

The Privacy Act permits us to disclose information without the consent of individuals for "routine uses"—that is, disclosures that are compatible with the purpose for which we collected the information. The proposed routine uses in the new system meet the compatibility criterion of the statute. We anticipate the disclosures under the routine uses will not result in any unwarranted adverse effects on personal privacy.

Dated: July 8, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

09-70-0008

SYSTEM NAME:

NATIONAL PROVIDER SYSTEM (NPS), HHS/HCFA/OIS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Health Care Financing Administration, Office of Information Services, HCFA Data Center, North Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

As defined by section 1171(3) of the Social Security Act (the Act), a health care provider is a provider of services as defined in section 1861(u) of the Act, a

provider of medical or other health services as defined in section 1861(s) of the Social Security Act, and any other person who furnishes health care services or supplies. For purposes of the NPS in assigning NPIs, the definition of health care provider is limited to those entities that furnish, or bill and are paid for, health care services in the normal course of business. The statutory definition of a health care provider is broad, with section 1861(u) containing the Medicare definition of an institutional provider (such as hospitals, home health agencies, etc.), and section 1861(s) containing the Medicare definition of other facilities and practitioners (such as assorted clinics, physicians, clinical laboratories, suppliers of durable medical equipment, other licensed/certified health care practitioners). This System of Records applies only to appropriately licensed or certified individual practitioners.

While the National Provider System will also include health care providers that are organizations (e.g., hospitals, pharmacies) and groups (entities composed of one or more individuals, as described earlier), these health care providers will not be addressed further in this systems notice because they are not covered under the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains a unique identifier for each health care provider (the NPI, which is assigned by the NPS) along with other information about the provider. This information includes other identifiers, name(s), demographic, educational/professional data, and business address data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 1173 and 1175 of the Act, as amended by Pub. L. 104-191, authorize the assignment of a unique identifier to all health care providers and the maintenance of a database on such health care providers. Sections 1874, 1816, 1842, 1876, 1880, 1881(c)(7), 1124, and 1124A of the Social Security Act authorize the assignment of a unique number to each Medicare provider and the maintenance of a database on such providers. Sections 1902(a)(4)(A), 1902(a)(6), 1902(a)(25), 1902(a)(27), 1902(a)(49), 1902(a)(59), 1903(r)(6)(H), and 1124 of the Act authorizes the assignment of a unique number to each Medicaid provider and the maintenance of a database on such providers. With respect to physicians who furnish services for which Medicare payment may be made, section 1842(r) of the Act mandates such a system. Similarly, section 1834(j) of the Act requires durable medical

equipment suppliers to obtain and renew a supplier number and limits the conditions under which HCFA may issue more than one number to a supplier (see section 131(a) of the 1994 Social Security Amendments). The Economy Act of 1932 as amended (31 U.S.C. 1535 and 1536) is the authority with respect to other Federal agencies.

PURPOSE(S):

The purpose of the system is to collect the information needed to uniquely identify an individual health care provider, to assign an NPI to that health care provider, to maintain and update the information about the health care provider, and to disseminate health care provider information in accordance with the provisions of the Privacy Act.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Section 552a(b) of the Privacy Act specifies a number of permitted releases for information held in systems of records. Section 552a(b)(3) permits an agency to identify additional routine uses, compatible with the purpose for which the information was collected, under which the information may be released without the consent of the individual to whom the information pertains. HCFA is identifying the following routine uses for information held in the National Provider System. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including, but not limited to, ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. Also, HCFA will require each prospective recipient of such information to agree in writing to certain conditions to ensure the continuing confidentiality of the information. More specifically, as a condition of each disclosure under these routine uses, HCFA will, as necessary and appropriate:

- (a) Determine that no other Federal statute specifically prohibits disclosure of the information;
- (b) Determine that the use or disclosure does not violate legal limitations under which the information was provided, collected, or obtained;
- (c) Determine that the purpose for which the disclosure is to be made;
 - (1) Cannot reasonably be accomplished unless the information is provided in individually identifiable form,
 - (2) Is of sufficient importance to warrant the effect on, or the risk to, the privacy of the individual(s) that

additional exposure of the record(s) might bring, and

(3) There is a reasonable probability that the purpose of the disclosure will be accomplished.

(d) Require the recipient of the information to;

(1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use or disclosure of the record or any part thereof. The physical safeguards shall provide a level of security that is at least the equivalent of the level of security contemplated in OMB Circular No. A-130 (revised), Appendix III, *Security of Federal Automated Information Systems* which sets forth guidelines for security plans for automated information systems in Federal agencies,

(2) Remove or destroy the information that allows subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished, consistent with the purpose of the request,

(3) Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed, and

(4) Make no further uses or disclosure of the information, except:

(i) To prevent or address an emergency directly affecting the health or safety of an individual;

(ii) For use on another project under the same conditions, provided HCFA has authorized the additional use(s) in writing; or

(iii) When required by law;

(e) Secure a written statement or agreement from the prospective recipient of the information whereby the prospective recipient attests to an understanding of, and willingness to abide by, the foregoing provisions and any additional provisions that HCFA deems appropriate in the particular circumstances; and

(f) Determine whether the disclosure constitutes a computer "matching program" as defined in 5 U.S.C. 552a(a)(8). If the disclosure is determined to be a computer "matching program," the procedures for matching agreements as contained in 5 U.S.C. 552a(o) must be followed.

Disclosure may be made:

1. To Federal and Medicaid health plans that are enumerators, their agents, and the NPS registry for the purpose of uniquely identifying and assigning NPIs to providers.

2. To entities implementing or maintaining systems and data files necessary for compliance with standards promulgated to comply with

title XI, part C, of the Social Security Act.

3. To a congressional office, from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

4. To another Federal agency for use in processing research and statistical data directly related to the administration of its programs.

5. To the Department of Justice, to a court or other tribunal, or to another party before such tribunal, when

(a) HHS, or any component thereof, or

(b) Any HHS employee in his or her official capacity; or

(c) Any HHS employee in his or her individual capacity, where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or

(d) The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components,

is party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party or interest, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

6. To an individual or organization for a research, demonstration, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or for the purposes of determining, evaluating and/or assessing cost, effectiveness, and/or the quality of health care services provided.

7. To an agency contractor for the purpose of collating, analyzing, aggregating or otherwise refining or processing records in this system, or for developing, modifying and/or manipulating automated information systems (ADP) software. Data would also be disclosed to contractors incidental to consultation, programming, operation, user assistance, or maintenance for ADP or telecommunications systems containing or supporting records in the system.

8. To an agency of a state Government, or established by state law, for purposes of determining, evaluating and/or assessing cost, effectiveness, and/or quality of health care services provided in the state.

9. To another Federal or state agency:

(a) As necessary to enable such agency to fulfill a requirement of a

Federal statute or regulation, or a state statute or regulation that implements a program funded in whole or in part with Federal funds.

(b) For the purpose of identifying health care providers for debt collection under the provisions of the Debt Collection Information Act of 1996 and the Balanced Budget Act of 1997.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on paper or magnetic media.

RETRIEVABILITY:

The records are retrieved by the NPI, employer identification number, other provider number, or as defined by query or report.

SAFEGUARDS:

For computerized records, safeguards established in accordance with Department standards and National Institute of Standards and Technology guidelines (e.g., security codes) will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resources Management (IRM) Circular #10, Automated Information Systems Security Program; and HCFA Automated Information System (AIS) Guide, Systems Security Policies; and OMB Circular No. A-130 (revised), Appendix III.

RETENTION AND DISPOSAL:

The records are retained indefinitely, except in the instance of an individual provider's death, in which case HCFA would retain such records for a 10-year period following the provider's death.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Information Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write the system manager, who will require the system name, provider name, and, for verification purposes, date of birth, and medical school (if applicable), to ascertain whether or not the individual's record is in the system. (These notification procedures are in accordance with Department regulation 45 CFR part 5b.)

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably

specify the record contents being sought. (These access procedures are in accordance with the Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

Contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Information from Federal health plan and Medicaid provider enrollment forms or applications that identify health care providers and give supporting information on same.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 98-20093 Filed 7-27-98; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Small Business Innovation Research Grant Applications Phase I and Phase II and Small Business Technology Transfer Grant Applications Phase I and Phase II

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), Office of the Director (OD) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register**, 12/23/97, page 67087 and allowed 60 days for public comment. No public comments were received. The purpose of this notice to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Small Business Innovation Research Grant Applications Phase I and Phase II, Small Business

Technology Transfer Grant Applications Phase I and Phase II. *Type of Information Collection Request:* Revision of OMB No. 0925-0195, expiration 07/31/98. *Need and Use of Information Collection:* This study will assess the PHS Small Business Innovation Research and NIH Small Business Technology Transfer Research Program Application Forms. *Frequency of Response:* Annually. *Affected Public:* Business or other for profit organizations. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,400. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 32. *Estimated Total Annual Burden Hours Requested:* 108,000. The annualized cost to respondents is estimated at: 0. There are no Capital Costs, Operating Costs, or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points. (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automate, electronic, mechanical or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instrument, contact: Mr. Sonny Kreitman, SBIR/STTR Program Coordinator, Rockledge II, 6701 Rockledge Drive, Room 6186, Bethesda Maryland 20892-7910 or call non-toll free number 301-435-2770 or Fax 301-480-0146 or e-mail your request to sk13n@nih.gov.