client declarations of income circumstances is by means of a computer match.

D. Categories of Records and Individuals Covered by the Match

VA will disclose information from the VA Compensation, Pension, and Education and Rehabilitation Records—VA (58 VA 21/22), contained in the Privacy Act Issuances, 1989 compilation, Volume II, Pages 918–922 and as amended in **Federal Register** 56 FR 15667, April 17, 1991.

ACF will match this information with KDSRS, NDSS, PDPW and TDHS Client Eligibility files.

E. Inclusive Dates of the Match

This computer match will begin no sooner than September 5, 1995, or 30 days from the date copies of the approved agreement, and the notice of the matching program are sent to the Congressional committee of jurisdiction under subsections (O)(2)(B) and (r) of the Privacy Act, as amended, or 30 days from the date the approved agreement is sent to OMB, whichever is later, provided no comments are received which result in a contrary determination. This is a one-time match and is not subject to renewal.

F. Address for Receipt of Public Comments or Inquiries

Individuals wishing to comment on this matching program should submit comments to the Acting Director, Office of Information Systems Management, Administration for Children and Families, Aerospace Building, 370 L'Enfant Promenade, SW, Washington, DC 20447.

[FR Doc. 95–19113 Filed 8–2–95; 8:45 am]

BILLING CODE 4184–01–M

Agency for Health Care Policy and Research

Public Meeting on Health Service Research: the Interface of Generalist and Specialist Health Care

AGENCY: Agency for Health Care Policy and Research (AHCPR).

ACTION: Notice of public meeting.

SUMMARY: A meeting is being held to discuss future directions of health services research related to the patterns, processes, and outcomes of medical referrals and consultations.

DATES: The meeting will be on Thursday, September 14, 1995, from 8:30 a.m. to 5:30 p.m. and Friday, September 15, from 8:30 a.m. to 12:00 p.m. Registration is required by August 30.

ADDRESSES: The meeting will be at the Madison Hotel, 15th and M Streets, N.W., Washington, D.C. 20005.

SUPPLEMENTARY INFORMATION:

I. Purpose

This meeting will focus on research that investigates patterns, processes, and outcomes of the referral of patients from primary care to specialist providers. The purposes of the meeting are (1) to identify gaps in current knowledge, and (2) to develop an agenda for future research. Of particular interest is the influence of new methods of organizing and financing health care on referral patterns and practices.

II. Agenda

The meeting will begin at 8:30 a.m. on September 14, with a review of the theoretical models and methods used in research that has focused on the referral of patients from primary care to specialist providers. Important problems and clinical issues involved in the care of patients referred from primary care to specialist care will be discussed. Presentations will be made by health services researchers, practicing clinicians, and representatives of managed care organizations and consumers. Questions and comments from the meeting participants will be encouraged.

The meeting participants will be assigned to small working groups which will meet concurrently during the afternoon of September 14. Each group will be asked to identify and discuss the important issues that need to be addressed by future research related to medical referrals and consultations. Reports and recommendations from working groups will be presented on Friday, September 15. A general discussion of a research agenda on medical referrals and consultations will conclude the meeting.

III. Arrangements for the September 14–15, 1995 Meeting

Individuals and representatives of organizations who would like to attend the meeting can obtain registration materials and information by calling 301–594–1369 extension 129, or by facsimile transmission at 301–594–3721. Facsimile cover sheets should be addressed to the attention of Ms. Kelly Morgan, Center for Primary Care Research, AHCPR, and should include the sender's name, organization, address, and telephone and facsimile numbers.

To register, submit the registration form and the required $100 registration fee by August 30 to Moshman Associates, the AHCPR contractor which is coordinating the meeting, at the address listed in the registration materials. Seating is limited to the first 100 registered individuals and will be reserved in the order in which both the registration form and the registration fee are received.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Ms. Kelly Morgan by August 30, at the telephone number listed above.

A brief, written summary of the presentations, discussions, and conclusions of the meeting will be made available in November 1995. To obtain a copy of this summary, please call the telephone number listed above after November 1.

Dated: July 27, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–19055 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 95E–0047]

Determination of Regulatory Review Period for Purposes of Patent Extension; Allergen Patch Test (Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test™)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Allergen Patch Test (Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test™) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biologic product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417)

and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product, Allergen Patch Test (Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test™) (multiple allergen test). T.R.U.E. Test™ is indicated primarily as an aid in the diagnosis of allergic dermatitis in patients whose histories suggest sensitivity to one or more of substances included on the T.R.U.E. Test™ panels. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for T.R.U.E. Test™ (U.S. Patent No. 4,836,217) from Pharmacia AB, and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 21, 1995, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of T.R.U.E. Test™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for T.R.U.E. Test™ is 2,966 days. Of this time, 1,601 days occurred during the testing phase of the regulatory review period, while 1,365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: October 10, 1986. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on October 10, 1986.

2. *The date application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: February 26, 1991. The applicant claims July 16, 1986, as the date the product license application (PLA) for T.R.U.E. Test™ (PLA 91–0118) was initially submitted. However, FDA records indicate that the two-panel test kit for the product that was ultimately approved was submitted on February 26, 1991. Therefore, the PLA was submitted on February 26, 1991.

3. *The date the application was approved*: November 21, 1994. FDA has verified the applicant's claim that PLA 91–0118 was approved on November 21, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, the applicant seeks 898 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 2, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 30, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–19060 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95F–0187]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

DATES: Written comments on the petitioner's environmental assessment by September 5, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), 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 5B4467) has been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

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