period, while 3,862 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 351 of the Public Health Service Act became effective*: June 20, 1984. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 20, 1984.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: October 5, 1987. FDA has verified the applicant's claim that the product license application (PLA) for Tisseel VH Kit (PLA 87–0509) was initially submitted on October 5, 1987.

3. *The date the application was approved*: May 1, 1998. FDA has verified the applicant's claim that PLA 87–0509 was approved on May 1, 1998.

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, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 25, 1999, 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 May 24, 1999, 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: November 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–31413 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–1017]

International Association of Color Manufacturers; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the International Association of Color Manufacturers has filed a petition proposing that the color additive regulations be amended to provide for the safe use of D&C Red No. 28 and its aluminum lake to color food and dietary supplements.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 9C0264) has been filed by the International Association of Color Manufacturers, c/o Daniel R. Thompson, P.C., 1620 I St., suite 925, Washington, DC 20006. The petition proposes to amend the color additive regulations to provide for the safe use of D&C Red No. 28 and its aluminum lake to color food and dietary supplements.

The agency has determined under 21 CFR 25.32(k) that this action is of a 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: November 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–31505 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1002]

Center for Biologics Evaluation and Research Medical Device Action Plan; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of November 2, 1998 (63 FR 58743). The document announced an upcoming public meeting requesting suggestions for improvements to the Center for Biologics Evaluation and Research's regulation of medical devices or reasons to maintain the current systems to protect public health. The notice inadvertently omitted the date and addresses for the submissions of comments after the meeting. This document corrects those omissions.

FOR FURTHER INFORMATION CONTACT: Kathy A. Eberhart, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–1317.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 2, 1998 (63 FR 58743), in FR Doc. 98–29185, FDA announced an upcoming public meeting requesting suggestions for improvements to the the Center for Biologics Evaluation and Research's regulations of medical devices or reasons to maintain the current systems to protect public health. The notice inadvertently omitted the date and address for the submissions of comments after the meeting.

1. On page 58743, in the third column, under the *Date and Time* caption, a second sentence is added to read ''Submit written comments by December 22, 1998.''

2. On the same page, after the ''*Location*'' portion, another paragraph is added to read ''*Addresses*: Submit by December 22, 1998, written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. A copy and received comments are available for public

examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.''

Dated: November 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31412 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0192]

Agency Information Collection Activities; Announcement of OMB Approval; Establishment and Product License Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Establishment and Product License Applications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 4, 1998 (63 FR 47299), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0124. The approval expires on November 30, 2001.

Dated: November 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31410 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–287 & HCFA–1491]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Home Office Cost Statement and Supporting Regulations in 42 CFR Section 413.17;

Form No.: HCFA–287 (OMB# 0938–0202);

Use: Medicare law permits components of chain organizations to be reimbursed for certain costs incurred by the Home Offices of the chain. The Home Office Cost Statement is required by the fiscal intermediary to verify Home Office Costs claimed by the components. This requires that the provider include in its costs, the costs incurred by the related organization in furnishing such services, supplies or facilities.

Frequency: Annually;

Affected Public: Not-for-profit institutions, Business or other for-profit;

Number of Respondents: 1,231;

Total Annual Responses: 1,231;

Total Annual Hours: 573,646.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Request for Medicare Payment—Ambulance and Supporting Regulations in 42 CFR Section 410.40 and 424.124;

Form No.: HCFA–1491 (OMB# 0938–0042);

Use: This form is used by physicians, suppliers, and beneficiaries to request payment of Part B Medicare services. It is used to apply for reimbursement for ambulance services.

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or households, and Not-for-profit Institutions;

Number of Respondents: 9,634,435;

Total Annual Responses: 9,634,435;

Total Annual Hours: 406,251.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 10, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–31536 Filed 11–24–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1051–N]

Medicare Program; December 14, 1998, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.