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