average of 10 incidences or less annually have been reported to FDA.

Section 812.36(c) and (f) estimates are based on FDA's experience with the treatment use of drugs and knowledge of the types of devices that may meet the treatment use criteria. FDA estimates that an average of six treatment use applications will be submitted each year. FDA estimates that it will take approximately 120 hours to prepare a treatment IDE and the total annual burden for preparing applications will be 720 hours. FDA also estimates that it will take approximately 20 hours to prepare a semiannual report, resulting in a total annual burden of 240 hours for annual reports.

III. Recordkeeping

Section 812.40 estimates are based on conversations with manufacturers, industry trade association groups, and businesses over the last 3 years. For significant risk device investigations, FDA has estimated that the recordkeeping burden for preparing an original IDE submission averages 10 hours for each original IDE submission. Similarly, through the same conversations previously mentioned, FDA has estimated recordkeeping for each supplement requires 1 hour. The recordkeeping burden for nonsignificant risk device investigations is difficult to estimate because nonsignificant risk device investigations are not required to be submitted to FDA. The IDE staff estimates that the number of recordkeepers for nonsignificant risk device investigations is equal to the number for active significant risk device investigations. The recordkeeping burden, however, is reduced for device nonsignificant risk studies. It is estimated that 600 recordkeepers will spend 6 hours each in maintaining these records.

Dated: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15059 Filed 6–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0201]

Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 30, 2003 (68 FR 32529). The document announced a public meeting to explore current methods being used to evaluate proprietary drug names to reduce medication errors due to similarity in drug names. The document published with inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–13591, appearing on page 32529 in the **Federal Register** of Friday, May 30, 2003, the following corrections are made:

1. On page 32530, in the first column, under ''**FOR FURTHER INFORMATION CONTACT**'', in the second paragraph, ''202–835–3533'' is corrected to read ''202–572–7751''.

2. On page 32530, in the third column, the first full sentence is corrected to read ''Speakers who wish to participate in the open public meeting must register by June 13, 2003.''

3. On page 32530, in the third column, under section III, the first sentence is corrected to read ''To speak at the meeting, you must preregister by June 13, 2003.''

Dated: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15058 Filed 6–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies 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: Transmissible Spongiform Encephalopathies 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 July 17, 2003, from 8 a.m. to 6 p.m., and on July 18, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 17, 2003, the committee will discuss the safety of bovine bone gelatin in oral and topical drugs, food and cosmetics. The committee will then discuss bovine spongiform encephalopathy in Canada and potential implications for FDA-regulated products. In the afternoon, the committee will hear presentations on transmissible spongiform encephalopathies (TSEs) and decontamination of medical equipment and facilities. On Friday, July 18, 2003, the committee will discuss designing, interpreting, and validating studies to evaluate reprocessing methods for removing TSE contamination from medical devices. In the afternoon, the committee will discuss methods to decontaminate facilities and equipment used to prepare human cellular and tissue products, and human blood products, including plasma derivatives, to reduce the theoretical risk of transmitting TSE agents.

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 July 10, 2003. Oral presentations from the public will be scheduled between approximately 11:35 a.m. and 11:55 a.m., and 1:55 p.m. and 2:25 p.m. on July 17, 2003; and between approximately 9:50 a.m. and 10:20 a.m., and 1:30 p.m. and 2 p.m. on July 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2003, 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