written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on October 5, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will be effective on that date.

Correction to the Direct final rule

Accordingly, pursuant to the authority delegated to me, the name of the Pratt Municipal Airport as published in the **Federal Register** on June 22, 2000 (65 FR 38721), **Federal Register** Document 00–15534; page 38722, column one) is corrected as follows:

§ 71.1 [Corrected]

On page 38722, in the first column, in the text header, correct the name of the Pratt Municipal Airport, KS, by removing Pratt Municipal Airport, KS, and substituting Pratt Industrial Airport, KS.

Issued in Kansas City, MO on August 17, 2000.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00–22039 Filed 8–28–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 98N–0144]

Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to correct inadvertent errors. This action is necessary to ensure the accuracy and consistency of the regulations.

DATES: This rule is effective August 29, 2000.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has discovered that errors have inadvertently become incorporated into the agency's regulations for biologics. In the **Federal Register** of October 20, 1999 (64 FR 56441), a final rule incorrectly revised § 56.102 (21 CFR 56.102) in paragraph (b)(11) instead of correctly revising paragraph (b)(10). Section 56.102 (b)(10) and (b)(11) were affected by this inadvertent error. This document corrects those errors.

List of Subjects in 21 CFR Part 56

Human research subjects, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 56 is amended as follows:

PART 56—INSTITUTIONAL REVIEW BOARDS

1. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

2. Section 56.102 is amended by revising paragraphs (b)(10) and (b)(11) to read as follows:

§ 56.102 Definitions.

* * * * *

(b) * * *

(10) An application for a biologics license, described in part 601 of this chapter.

(11) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in part 601 of this chapter.

* * * * *

Dated: August 4, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21895 Filed 8–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 99N–1819]

RIN 0910–AA01

Topical Antifungal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) topical antifungal drug products. The amendment makes a minor change in the indications for these drug products. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This regulation is effective May 16, 2002. The compliance date for products with annual sales less than $25,000 is May 16, 2003. The compliance date for all other OTC drug products is May 16, 2002.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1993 (58 FR 49890), FDA published a final monograph for OTC topical antifungal drug products in part 333 (21 CFR part 333), subpart C. That monograph includes labeling in § 333.250. Section 333.250(b)(1) contains the following introductory language for the indications statement: (Select one of the following: ''Treats,'' ''For the treatment of,'' ''For effective treatment of,'' ''Cures,'' ''For the cure of,'' ''Clears up,'' or ''Proven clinically effective in the treatment of''). Section 333.250(b)(2) contains similar language for products labeled for the prevention of athlete's foot.

In the **Federal Register** of July 22, 1999 (64 FR 39452), FDA published a proposed amendment of the monograph for OTC topical antifungal drug products to revise the indications in § 333.250(b)(1)(i) and (b)(2)(i). The proposed revision added the word ''most'' after the introductory parenthetical ''Select one of the following'' choices and before the name