form of prospectus used after the end of its first fiscal year, if that prospectus or related Statement of Additional Information contains audited financial statements covering a period of at least six months; otherwise, the information required by this Item must be included in the first form of prospectus used after its second fiscal year.

6. If the Registrant is a series company, include the information required by this Item for each series.

* * * * *

16. In the case of Alternative I, by adding Item 5A to Form N–1A (17 CFR 239.15A and 274.11A) to read as follows:

* * * * *

Item 5A. Management's Discussion and Analysis of Investment Performance

(a) Discuss and analyze the Registrant's performance during its last fiscal year in relation to its investment objectives. Indentify and evaluate the factors that materially affected performance. Evaluate the effectiveness of significant investment techniques and strategies used to pursue the investment objectives, and describe any material effects that those techniques and strategies had on total return.

(b) Discuss the impact that any formal or informal policy as to the maintenance of a specified level of distributions to shareholders had on investment strategies of the fund and per share net asset value during the Registrant's last fiscal year.

Instructions:

1. The purpose of the discussion and analysis is to provide investors information relevant to an assessment of the Registrant's performance, given its investment objectives and policies. The Registrant should use an approach that will enable investors to best understand how it has achieved its performance. Include a statement explaining that past performance is not predictive of future performance.

2. The discussion and analysis in response to paragraph (a) of this Item should focus only on factors, techniques, and strategies materially affecting performance during the last fiscal year. These factors, techniques, and strategies may (but are neither limited to nor required to) include the following: developments in the markets in which the portfolio securities traded, composition of the Registrant's portfolio [*e.g.*, types of issuers (capitalization, industry grouping, foreign or domestic), types of securities, quality of portfolio securities, average maturity of portfolio securities, cash equivalent position], net asset value of the fund, expense ratio, portfolio turnover, sales and redemption trends, currency fluctuations, hedging transactions, whether the fund assumed at any time a temporary defensive position.

3. The Registrant must include the information required by this Item in the first form of prospectus used after the end of its first fiscal year, if that prospectus or related Statement of Additional Information contains audited financial statements covering a period of at least six months; otherwise, the information required by this Item must be included in the first form of prospectus used after its second fiscal year.

4. If the Registrant is a series company, include the information required by this Item for each series.

By the Commission.

Dated: January 8, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–836 Filed 1–12–90; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 310, 314, and 320

[Docket No. 85N–0214]

RIN 0905–AB63

Abbreviated New Drug Application Regulations; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 9, 1990, the comment period for the proposed rule to implement Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (July 10, 1989; 54 FR 28872). The proposal provides for the submission of abbreviated new drug applications (ANDA's) for generic versions of drug products. This document extends for 90 days the time for submission of comments on the proposal.

DATE: Comments by April 9, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, or, Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8049.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 10, 1989 (54 FR 28872), FDA issued a proposed rule to implement Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417), which amends section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). The proposal provides for the submission of ANDA's for generic versions of drug products. These new provisions are intended to benefit consumers by making generic drug products available more quickly. The proposal gave interested persons an opportunity to submit written comments for 90 days (by October 10, 1989).

In the **Federal Register** of October 11, 1989 (54 FR 41629), FDA extended the comment period to January 9, 1990, in response to requests from several organizations. These organizations requested additional time to respond adequately to the proposal because of complex issues and questions that need careful analysis and evaluation. FDA carefully evaluated the requests and determined that a 90-day extension to the comment period for the preparation and submission of meaningful comments to a detailed and complex proposed rule was in the public interest.

FDA has received another request to extend the comment period for an additional period of time. The request asked that the comment period be extended to permit the generic drug industry to prepare and submit to FDA meaningful comments.

FDA has carefully considered this request and has determined that, because of the complexity of the proposed rule and the interest in the generic drug program, there has been insufficient time for interested persons to evaluate the proposal and to submit meaningful comments to the agency. Accordingly, the comment period for submission of comments by any interested person is extended to April 9, 1990.

Interested persons may, on or before April 9, 1990, submit written comments regarding this proposal to the Dockets Management Branch (address above). 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 9, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90–980 Filed 1–10–90; 2:47 pm]

BILLING CODE 4160–01–M

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21 CFR Parts 310, 343, and 369

[Docket No. 77N–0094]

RIN 0905–AA06

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Extension of Reply Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking; extension of reply comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to March 16, 1990, the period for comments on new data for the notice of proposed rulemaking to establish conditions under which over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products are generally recognized as safe and effective and not misbranded. This action responds to a request to extend the reply comment period for an additional 60 days to allow more time for interested persons to review and respond to the extensive comments and new data that have been submitted.

DATE: Written comments by March 16, 1990.

ADDRESSES: Written comments to the Docket Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 16, 1988 (53 FR 46204), FDA issued a notice of proposed rulemaking to establish conditions under which OTC internal analgesic, antipyretic, and antirheumatic drug products are generally recognized as safe and effective and not misbranded. This notice of proposed rulemaking, which was based on the agency's evaluation of the recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products and the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on those recommendations, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until November 16, 1989, to submit new data and until January 16, 1990, to comment on the new data.

In response to the proposal, Bristol-Myers Products requested a 60-day extension of the reply comment period to allow adequate time for the company to thoroughly review and formulate appropriate comprehensive responses and comments concerning the new data submitted. The company noted that no less than seven respondents had submitted comments and/or new data on matters so diverse as label warnings, dissolution rate specifications, and safety of acetaminophen. The company added that no less than 15 reports of clinical studies had been submitted. The company concluded that this extension of time to prepare a more thorough and comprehensive evaluation of these comments and new data would benefit both the company and the agency.

FDA has carefully considered the request. The agency acknowledges that a large amount of data have been submitted, much of it in November 1989. The agency believes that additional time for reply comments on the massive amount of data submitted is in the public interest, and may be of assistance in establishing conditions under which OTC internal analgesic, antipyretic, and antirheumatic drug products are generally recognized as safe and effective and not misbranded. Thus, the agency considers a general extension of the reply comment period for 60 days to be appropriate.

Interested person may, on or before March 16, 1990, submit to the Dockets Management Branch (address above) written comments on the new data submitted to the notice of proposed rulemaking. Three 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 10, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–1029 Filed 1–11–90; 10:42 am]

BILLING CODE 4160–01–M

21 CFR Part 1020

[Docket No. 82N–0274]

Federal Performance Standard for Diagnostic X-Ray Systems and Their Major Components; Proposed Amendments; Correction

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration is making technical corrections to the proposed rule which would amend the Federal performance standard for diagnostic X-ray systems and their major components. The proposed rule appeared in the **Federal Register** of October 17, 1989 (54 FR 42674).

FOR FUTHER INFORMATION CONTACT: Samuel Fleisher, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4874.

In FR Doc. 89–24366, appearing at page 42674, in the **Federal Register** of Tuesday, october 17, 1989, the following corrections are made:

1. On page 42681, in the first column, in the third and fifth paragraphs, and in the second column, in lines 3 and 10, and in the first full paragraph, "§ 1020.32(d)(4)" is corrected to read "current § 1020.32(d)(3)" wherever it appears.

§ 1020.31 [Corrected]

2. On page 42688, in the first column, in § 1020.31(c)(1), in the ninth line, "$X_1 - X_2 \leq 0.10(X_1 + X_2)$" is corrected to read "absolute $(X_1 - X_2) \leq 0.10(X_1 + X_2)$", and in § 1020.31(c)(2), in the ninth line, "$X_1 - X_2 0.10(X_1 + X_2)$" is corrected to read "absolute $(X_1 - X_2) \leq 0.10(X_1 + X_2)$".

§ 1020.32 [Corrected]

3. On page 42691, in the second column, in § 1020.32(d)(1) in the first sentence, the phrase "(C/kg)(10 roentgens per minute)(10 R/min)" is corrected to read "C/kg per minute (10 R/min)".

Dated: January 5, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–883 Filed 1–12–90; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 7 and 602

[INTL–704–87]

RIN 1545–AL35

Certain Corporate Distributions to Foreign Corporations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue, the Internal Revenue Service is issuing temporary Income Tax Regulations that add new sections necessary to implementing section 367(e) (1) and (2) of the Internal Revenue Code of 1986, relating to certain corporate distributions to foreign shareholders. These provisions affect the taxability of both corporate distributors and shareholder