Application for Alien Employment Certification and H–2A Petition, which consolidated two current forms, ETA 750 Application for Alien Employment Certification) and INS I–129 (Petition for Nonimmigrant Workers). The NPRM also set forth the implementation of a new fee schedule to collect a combined fee for processing the petition and labor certification application. It is contemplated that under the administrative procedures arrived at by INS and the Employment and Training Administration to implement the delegation of the petition authority from INS to the Department, DOL will collect the petition fee on behalf of INS and will be reimbursed by INS for the costs involved in processing the H–2A petition.

The INS reopened and extended the comment period at 65 FR 50166 (August 17, 2000) on a proposed rule published concurrently at 65 FR 43535 (July 13, 2000) with its final rule delegating the authority to adjudicate petitions to DOL. The INS proposed rule provided, among other things, that all petition requests and extensions of stay and change of status petitions must be filed with DOL and the current INS petition fee will be collected by DOL as part of a combined fee.

Commenters raised a number of issues about the proposed rules. The comments received by the Department as a result of the August 17, 2000, reopening and extension of the proposed rule did not provide sufficient information to permit the Department to draft a final rule concerning a number of issues, such as the design of the new form and the fee structure. Consequently, the Department intends in the near future to again reopen and extend the comment period on the July 13, 2000, NPRM. In a document published elsewhere in this issue of the **Federal Register**, the Department is reopening and extending the comment period on the NPRM. In another document, the Department is announcing informal briefings to allow agricultural workers and employers and other interested parties to communicate directly with the Department regarding the proposed rule changes which would require employers to submit fees for temporary labor certification and the associated H–2A petition with a consolidated application form at the time of filing, and as indicated above, sets forth a new fee structure for the labor certification.

Finalizing the proposed rules is essential to the effective implementation of any delegation of authority to DOL to adjudicate petitions for temporary employment of nonimmigrant aliens in the United States. Allowing the Final Rule to become effective without finalizing action on the proposed rule published by the Department would lead to administrative uncertainty and result in confusion on the part of employers, agricultural workers, and other interested parties. Accordingly, the Department has concluded good causes exists to defer the effective date of the July 13, 2000, Final Rule until the rulemaking on the companion proposal is completed. At this time we are extending the effective date of the final rule published at 65 FR 43538 for one year, until October 27, 2002. The regulatory certifications set forth in the July 13, 2000, Final Rule apply to this deferral as well.

Signed at Washington, DC, this 24th day of September 2001.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. 01–24208 Filed 9–26–01; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration.

21 CFR Part 341

[Docket No. 76N–052G]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Partial Final Rule for Combination Drug Products Containing a Bronchodilator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that cough-cold combination drug products containing any oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient are not generally recognized as safe and effective and are misbranded for over-the-counter (OTC) use. FDA is issuing this final rule after receiving no public comments on the agency's proposed nonmonograph status of these specific combination drug products, which was issued in the form of a tentative final monograph for OTC cough-cold combination drug products. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This regulation is effective October 29, 2001.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, l976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The Panel placed the combination of an oral bronchodilator with either an analgesic-antipyretic, anticholinergic, antihistamine, or antitussive (when the product is labeled only for cough associated with asthma) ingredient in Category II (not generally recognized as safe and/or effective) (41 FR 38312 at 38326).

The agency concurred with the Panel in the tentative final monograph for cough-cold combination drug products (53 FR 30522 at 30556, August 12, 1988). The agency also classified the combination of caffeine and ephedrine or pseudoephedrine in Category II (53 FR 30522 at 30557). No comments on these specific combinations were submitted in response to the tentative final monograph.

The current monograph oral bronchodilator active ingredients are ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride (21 CFR 341.16(a), (b), (c), and (f)). The agency is not aware of any OTC drug products currently marketed containing an oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient.

II. The Agency's Conclusion

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded.

Two principal conditions examined during the review are allowable ingredients and allowable labeling. The Panel evaluated the submitted data on active ingredients in combination products from the standpoint of safety and effectiveness and, based on its evaluation, recommended specific combinations of ingredients from the same and different pharmacologic groups. The Panel classified a number of cough-cold combinations as Category II (41 FR 38312 at 38326) and considered medical rationale and drug interaction in making these recommendations.

In the tentative final monograph for OTC cough-cold combination drug products (53 FR 30522 at 30556 to 30557), the agency agreed with the Panel's recommended Category II status of any oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient. The agency invited interested persons to submit written comments and new data demonstrating the safety and effectiveness of those conditions not classified in Category I (53 FR 30522 at 30560). The agency did not receive any comments in response to its request for such information concerning the proposed Category II status of any of the above-mentioned OTC cough-cold combination drug products containing an oral bronchodilator.

Accordingly, in this final rule the agency is finalizing the nonmonograph status of any oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient. Thus, any drug product labeled, represented, or promoted for use as an OTC cough-cold combination drug that contains any oral bronchodilator active ingredients in combination with any of these specific active ingredients may be considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352). These specific combination drug products can not be marketed for OTC cough-cold use unless they are the subject of an approved application under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314). Any OTC cough-cold combination drug product included in new § 310.545(a)(6)(iv)(D) that is initially introduced or initially delivered for introduction into interstate commerce after the effective date stated in § 310.545(d)(33) of this final rule that is not in compliance with the regulations is subject to regulatory action.

III. Analysis of Impacts

The agency did not receive any comments in response to its request in the tentative final monograph (53 FR 30522 at 30560) for specific comment on the economic impact of this rulemaking. FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The purpose of this final rule is to declare any oral bronchodilator active ingredient in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient as not generally recognized as safe and effective. The agency does not believe that any of these combination drug products are currently marketed OTC. Therefore, this final rule should have no economic impact on any manufacturer.

Under the Unfunded Mandates Reform Act, FDA is not required to prepare a statement of costs and benefits for this final rule because this final rule is not expected to result in an expenditure that would exceed $100 million adjusted for inflation in any one year.

The agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

IV. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by adding paragraph (a)(6)(iv)(D), by revising paragraph (d) introductory text, by adding and reserving paragraph (d)(32), and by adding paragraph (d)(33) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(6) * * *

(iv) * * *

(D) Approved as of October 29, 2001. Any oral bronchodilator active ingredient (e.g., ephedrine, ephedrine

hydrochloride, ephedrine sulfate, racephedrine hydrochloride, or any other ephedrine salt) in combination with any analgesic(s) oranalgesic-antipyretic(s), anticholinergic, antihistamine, oralantitussive, or stimulant active ingredient.

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initiallyintroduced or initially delivered for introduction intointerstate commerce after the dates specified in paragraphs(d)(1) through (d)(33) of this section.

* * * * *

(32) [Reserved]

(33) October 29, 2001, for products subject to paragraph (a)(6)(iv)(D) of this section.

Dated: September 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24127 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8964]

RIN 1545–AY55

Liabilities Assumed in Certain Corporate Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations relating to the assumption of liabilities in certain corporate transactions under section 301 of the Internal Revenue Code. These final regulations affect corporations and their shareholders. Changes to the applicable law were made by the Miscellaneous Trade and Technical Corrections Act of 1999.

DATES: *Effective Date*: These regulations are effective September 27, 2001.

Applicability Date: For dates of applicability, see the Effective Date portion of the preamble under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Douglas Bates (202) 622–7550 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Changes to the applicable law were made by the Miscellaneous Trade and Technical Corrections Act of 1999, Public Law 106–36 (113 Stat. 127). On January 4, 2001, temporary regulations (TD 8924) were published in the **Federal Register** (66 FR 723) under section 301 of the Internal Revenue Code, relating to liabilities assumed in connection with a distribution of property made by a corporation with respect to its stock. A notice of proposed rulemaking cross-referencing the temporary regulations was published in the **Federal Register** for the same day (66 FR 748). No public hearing was requested or held.

No written comments responding to the notice were received. This document adopts, without substantive change, final regulations with respect to the notice of proposed rulemaking.

Effective Date

The regulations apply generally to distributions occurring after January 4, 2001. The regulations also apply to distributions occurring on or prior to January 4, 2001, if the distribution is made as part of a transaction described in, or substantially similar to, the transaction in Notice 99–59 (1999–2 C.B. 761), including transactions designed to reduce gain. Under section 7805(b)(3), the Secretary may provide that any regulation may take effect or apply retroactively to prevent abuse. These regulations are being applied retroactively to prevent the abuse described in Notice 99–59. No inference should be drawn regarding the tax treatment of distributions not covered by these regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

It is hereby certified that these final regulations do not have a significant economic impact on a substantial number of small entities. These final regulations under section 301 address distributions by corporations in which liabilities are assumed by the shareholders or in which the distributed property is subject to liabilities. These final regulations provide that the amount of a distribution under section 301 will be reduced by the amount of any liability that is treated as assumed by the distributee within the meaning of section 357(d).

These regulations apply to persons receiving distributions of property in which the property is subject to a liability, or in which liabilities are assumed by the distributee. These regulations, however, will affect only those persons described in the preceding sentence that would have, but for the regulations, considered liabilities to have been assumed in circumstances other that those described in section 357(d). Therefore, most businesses will not be affected by the final regulations in any given year. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking accompanying these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Drafting Information

The principal author of these regulations is Michael N. Kaibni of the Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *. Section 1.301–1 also issued under 26 U.S.C. 357(d)(3). * * *

Par. 2. Section 1.301–1 is amended by revising paragraph (g) to read as follows:

§ 1.301–1 Rules applicable with respect to distributions of money and other property.

* * * * *

(g) *Reduction for liabilities*—(1) *General rule*. For the purpose of section 301, no reduction shall be made for the amount of any liability, unless the liability is assumed by the shareholder within the meaning of section 357(d).

(2) *No reduction below zero*. Any reduction pursuant to paragraph (g)(1) of this section shall not cause the amount of the distribution to be reduced below zero.

(3) *Effective dates*—(i) *In general*. This paragraph (g) applies to distributions occurring after January 4, 2001.

(ii) *Retroactive application*. This paragraph (g) also applies to