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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

65 FR 38191  
6.20.00

**21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701**

**[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]**

**RIN 0910-AA79**

**Over-the-Counter Human Drugs; Labeling Requirements; Partial Extension of Compliance Dates**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; partial extension of compliance dates.

Comments 9.18.00

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**SUMMARY:** The Food and Drug Administration (FDA) is providing a partial extension of the compliance dates for its final rule that appeared in the **Federal Register** of March 17, 1999. The final rule established a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. That final rule requires all OTC drug products to have the new, easy-to-read format and the revised labeling requirements within prescribed implementation periods. This partial extension provides 1 additional year for implementation for specific types of OTC drug products to be in compliance with the final rule.

**DATES:**

*Effective Date:* This rule is effective [insert date 30 days after date of publication in the **Federal Register**].

*Compliance Dates:* For compliance dates, see section III of the **SUPPLEMENTARY INFORMATION** section of this document. Submit written comments by [insert date 90 days after date of publication in the **Federal Register**].

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**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and standardized content requirements for the labeling of OTC drug products. Those requirements are codified in § 201.66 (21 CFR 201.66).

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. This includes products marketed under a final OTC drug monograph, an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), and OTC drug products for which there is no final OTC drug monograph or approved drug application.

The agency provided different implementation dates by which OTC drug products had to be in compliance with the new requirements. These dates varied according to the regulatory status of the products (64 FR 13254 at 13273 and 13274).

*A. Products in the OTC Drug Review*

Products marketed under final OTC drug monographs had to comply with the final rule by April 16, 2001. Products for which a final monograph became effective on or after April 17, 1999 had to comply as of: (1) The applicable implementation date for that final monograph; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever occurs first.

Combination drug products in which all of the active ingredients are the subject of a final monograph or monographs had to comply with the final rule as of April 16, 2001. Combination products in which one or more active ingredients are the subject of a final monograph, and one or more ingredients are still under review as of the effective date of the final rule, had to comply as of the implementation date for the last applicable final monograph for the combination, or as of April 16, 2001, whichever is earlier. Combination products in which none of the active ingredients is the subject of a final monograph or monographs as of the effective date of the final rule had to comply as of: (1) The implementation date of the last applicable final monograph for the combination; (2) the next major revision to any part of the label or labeling after April 16, 2001; or (3) April 18, 2005, whichever comes first.

*B. Products Marketed Under NDA's and ANDA's*

Products that are the subject of an approved drug application (NDA or ANDA) before April 16, 1999, had to comply as of April 16, 2001. Products that become the subject of an approved NDA or ANDA on or after April 16, 1999, had to immediately comply with the final rule.

*C. Additional Provisions*

Any OTC drug product that was not described in section I.A and I.B above had to comply with the final rule as of: (1) The next major revision to any part of the label or labeling after April 16, 2001; or (2) April 18, 2005, whichever occurs first.

Products (including combinations) marketed under a final OTC drug monograph or monographs, or under an NDA or ANDA, with annual sales of less than \$25,000 had to comply with the final rule as of April 16, 2002. This extra time was intended to provide marketed products with a low level of distribution 1 additional year to comply with the final rule.

Irrespective of the regulatory status of the product, the agency strongly encouraged all manufacturers, distributors, and packers of OTC drug products to voluntarily implement the new content and format requirements as soon as possible, particularly when existing labeling is

exhausted and relabeling would occur in the normal course of business. The agency also encouraged sponsors of products marketed under NDA's and ANDA's to submit any required labeling supplements as soon as possible to ensure timely review.

The agency provided a chart that summarized the time periods within which the various categories of marketed OTC drug products must be in compliance with the final rule (64 FR 13254 at 13274). Unless otherwise stated, all time periods in the chart began on the effective date of the final rule.

In the **Federal Register** of April 15, 1999 (64 FR 18571), the agency published a correction to the final rule and corrected the effective date from April 16, 1999, to May 16, 1999. While the agency did not discuss the implementation plan and the compliance dates for the final rule (or the chart at 64 FR 13274) in this correction, the correction had the effect of changing the compliance dates for the final rule: (1) April 16, 1999, to May 16, 1999; (2) April 16, 2001, to May 16, 2001; (3) April 16, 2002, to May 16, 2002; and (4) April 18, 2005, to May 16, 2005.

## **II. Citizen Petitions Requesting Additional Implementation Time**

Following publication of the final rule, the Consumer Healthcare Products Association (CHPA) and The Cosmetic, Toiletry, and Fragrance Association (CTFA) submitted citizen petitions (Refs. 1 and 2) requesting a 2-year extension of time for compliance with the final rule, i.e., extending the May 16, 2001, date to May 16, 2003, and the May 16, 2002, date to May 16, 2004. No change to the May 16, 2005, date was requested. CHPA also requested a stay of the final rule for those products that had to immediately begin to comply with the rule (i.e., OTC drug products approved under an NDA or ANDA after May 16, 1999) until several implementation issues described in the CHPA petition were resolved and companies were given sufficient time to incorporate FDA's clarification into OTC drug product labeling. The petitions discussed a number of issues CHPA and CTFA considered as "open" or pending: (1) The use of columns in labeling, (2) the protection of trade dress, (3) the use of type sizes smaller than 6.0 points, (4) the labeling of single use and convenience packages or a categorical small package exemption, (5) the use

of extended text labeling, (6) the exemption process, and (7) harmonizing the new "Drug Facts" labeling with existing cosmetic labeling.

The agency answered these citizen petitions on February 4, 2000 (Refs. 3 and 4). The agency addressed the issues that were raised and stated that most of the issues (columns, the exemption process, the labeling of single use and convenience products) had been addressed or would soon be addressed through the agency's guidance process. One issue (trade dress) had been addressed through a recent amendment to the final rule (65 FR 7, January 3, 2000). The agency did not consider the remaining issues as presenting a significant obstacle toward industry-wide implementation of the final rule, as demonstrated by the large numbers of products that are able to comply with the rule.

### **III. The Agency's Final Conclusions**

The agency concluded that a stay of the final rule or a blanket extension of 2 years is excessive and is not consistent with the public's interest in having clear, readable OTC drug product labeling. Also, recognizing that guidance documents may prove helpful to industry in the transition to the new labeling format, and that the agency intends to issue at least one more guidance document (on exemptions and deferrals), the agency concluded that an extension of the May 16, 2001, date by 1 year to May 16, 2002 (and a corresponding extension of the May 16, 2002, date for products with annual sales of less than \$25,000 to May 16, 2003) is justified. The request for a stay of the final rule for products marketed under an NDA or ANDA approved after May 16, 1999, was denied.

The agency is restating below in table 1, the implementation chart that appeared in the final rule (64 FR 13254 at 13274). This chart is updated to show the new implementation compliance dates for the final rule. In addition, the agency is making one minor change in the implementation chart. For combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before May 16, 1999, and at least one applicable monograph is finalized on or after May 16, 1999, the time period is stated as "Within the period

specified in the last applicable monograph to be finalized, or by May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000), whichever occurs first.” The agency recognizes that some final monographs may be finalized close to the May 16, 2002, date. If that occurred, relabeling might be required at two closely related time intervals by two different final rules. The agency would be aware of that possibility when the last applicable monograph is published and would make allowance there to avoid this dual relabeling within a short time period. Therefore, the agency is adding at the end of the time period for this specific type of combination product in the implementation chart the words “unless the last applicable monograph to be finalized specifies a later date.” This language should alleviate any possible ambiguities that might have existed as to when relabeling required by two different rules would have to occur.

TABLE 1.—IMPLEMENTATION CHART

Products	Time Periods
Single entity and combination products subject to drug marketing applications approved before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000).
Single entity and combination products subject to drug marketing applications approved on or after May 16, 1999.	Immediately upon approval of the application.
Single entity products subject to an OTC drug monograph finalized before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000).
Single entity products subject to an OTC drug monograph finalized on or after May 16, 1999.	Within the period specified in the final monograph. However, if a monograph has not been finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs were finalized before May 16, 1999.	By May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000).
Combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before May 16, 1999, and at least one applicable monograph is finalized on or after May 16, 1999.	Within the period specified in the last applicable monograph to be finalized, or by May 16, 2002 (or by May 16, 2003, if annual sales of the product are less than \$25,000), whichever occurs first, unless the last applicable monograph to be finalized specifies a later date.
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs are finalized on or after May 16, 1999.	Within the period specified in the last applicable monograph to be finalized. However, if the last monograph is not finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.
All other single entity and combination OTC drug products (e.g., products in the OTC drug review that are not yet the subject of proposed OTC drug monographs).	If a monograph has not been finalized as of May 16, 2002, then the product must comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.

#### IV. Extension of Compliance Dates for Other Labeling Revisions

The final rule also contained a number of other required labeling revisions in 21 CFR parts 201, 330, 331, 341, 346, 355, 358, 369, and 701 (64 FR 13254 at 13291, 13292, and 13294 to 13297). For any of those labeling revisions that would have had to be implemented by May 16,

2001, or May 16, 2002, as a result of complying with § 201.66, the agency is also providing a 1-year extension of time for implementation.

## **V. Analysis of Impacts**

The economic impact of the final rule was discussed in the final rule (64 FR 13254 at 13276 to 13285). This partial extension of the compliance dates provides additional time for companies to relabel their products and be in compliance with the final rule. This extension will also reduce label obsolescence as companies will have additional time to use up more existing labeling. Thus, extending some of the compliance dates by 1 year will significantly reduce the economic impact on industry.

FDA has examined the impacts of this final rule (partial extension of the compliance dates) under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) (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. Title II 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 in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. This 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. As discussed in this section, FDA has determined that this final rule will not have a significant

economic impact on a substantial number of small entities. Further, because this final rule makes no mandates on government entities and will result in expenditures less than \$100 million in any one year, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to provide a partial extension of some of the compliance dates by which manufacturers need to relabel their products. This final rule provides 1 additional year to relabel many products. Accordingly, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## **VI. Good Cause**

In its responses to the citizen petitions (Refs. 3 and 4), the agency set forth in detail its finding that a stay of the rule, or a blanket extension of 2 years, is excessive and is not consistent with the public's interest in having clear, readable OTC drug labeling. However, in recognition of the fact that there are several pending guidance documents that may prove helpful in the transition to the new format, and that at least one on exemptions and deferrals has yet to issue, the agency concluded that an extension of the May 16, 2001, primary implementation date by 1 year to May 16, 2002 (and the corresponding implementation date for products with annual sales less than \$25,000 to May 16, 2003) was justified. Since the agency is extending the compliance date of the OTC labeling final rule based on the citizen petition responses and because these changes are nonsubstantive in nature, FDA finds that notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 553(b) and (d)). More than 3 months have passed since the agency issued the citizen petition responses and the agency has received no adverse correspondence or comments with respect to its decision. Therefore, the agency is now amending the compliance date of the final rule. However, in accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this partial extension of the compliance dates should be modified or revoked.

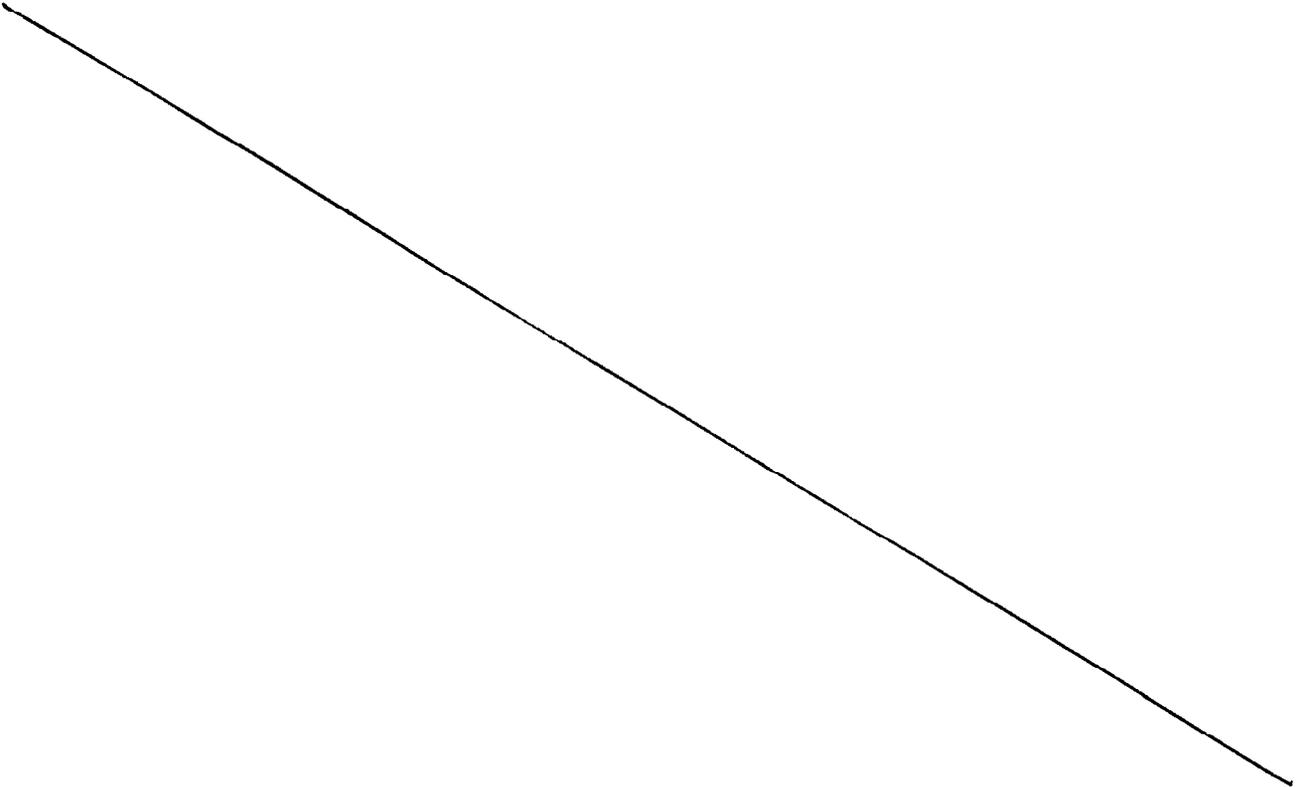
## VII. References

1. Comment No. CP2, Docket No. 98N-0337, Dockets Management Branch.
2. Comment No. CP1, Docket No. 99P-4617, Dockets Management Branch.
3. Letter from W. K. Hubbard, FDA, to B. N. Kuhlik and M. S. Labson, Covington & Burling, coded PAV2, Docket No. 98N-0337, Dockets Management Branch.
4. Letter from W. K. Hubbard, FDA, to E. E. Kavanaugh, CTFA, coded PAV1, Docket No. 99P-4617, Dockets Management Branch.

This final rule (partial extension of compliance dates) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority delegated to the Commissioner of Food and Drugs.

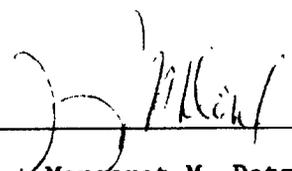
## VIII. Comments

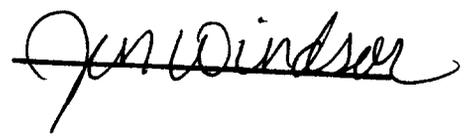
Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this final rule by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit



one copy. Comments are to be identified with the docket numbers 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: June 12, 2000  
June 12, 2000

  
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Margaret M. Dotzel  
Associate Commissioner for Policy

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