

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 77N-094W]

Display Date	3/12/99
Publication Date	3/17/99
Certifier	Jen Winder

12:40 pm

15 9 1.2

11

Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning; Final Rule; Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; compliance date.

---

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a compliance date of October 22, 1999, for the regulation that published in the Federal Register of October 23, 1998 (63 FR 56789). The regulation established warning statements that advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. The compliance date applies to all affected OTC drug products, whether marketed with or without an approved application. FDA is taking this action in response to correspondence and a citizen petition requesting more time to relabel these products.

**DATES:** 21 CFR 201.322, published on October 23, 1998 (63 FR 56789), is effective April 23, 1999; but compliance is not required until October 22, 1999.

**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:**

NFR 2

## I. Background

In the Federal Register of November 14, 1997 (62 FR 61041), FDA published a proposed amendment of part 201 (21 CFR part 201) to establish alcohol warnings for all OTC drug products labeled for adult use containing internal analgesic/antipyretic active ingredients. The agency stated that it may change the wording of the proposed warnings or not require them as a result of comments filed in response to the proposal. Because it wished to encourage the voluntary use of the proposed warning statements, the agency advised that manufacturers would be given ample time after publication of a final rule to use up any labeling printed in conformance **with the proposal** (62 FR 61041 at 61052).

In the **Federal Register** of October 23, 1998 (63 FR 56789), FDA issued a final rule amending **part 201** and establishing in §201.322 a required alcohol warning for OTC drug products containing internal analgesic/antipyretic active ingredients. The final rule requires manufacturers to add certain new warnings for any OTC drug product, labeled for adult use, containing any internal analgesic/antipyretic active ingredients (including, but not limited to, acetaminophen, aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate) alone or in combination and marketed with or without an approved application. The wording of the warnings in the final rule was different than the wording in the proposal. The final rule specified an effective date of April 23, 1999, for any OTC drug product subject to this section.

## II. Summary of Comments Received

In response to the final rule, the agency received several comments (Ref. 1) and a citizen petition (Ref. 2) requesting more time to implement the new required alcohol warnings and a mechanism by which manufacturers may petition the agency for a variance or extension of time to comply with the regulation's 6-month implementation date. The comments were submitted by several large manufacturers of brand name OTC internal **analgesic/antipyretic** drug products and a manufacturer of a large number of private label OTC internal **analgesic/antipyretic** drug products.

The comments stated that relabeling procedures generally take longer than the 6 months provided for in the final rule and that the companies simply lack the needed manpower and equipment to comply by April 23, 1999.

The comments added that the implementation period for the new rule must ensure that label integrity is not compromised or done haphazardly. The comments stated that 6 months is an insufficient period of time for a number of companies to accomplish the relabeling, and the short timeframe does not promote emphasis on labeling integrity and good manufacturing practice compliance. All of the comments expressed concern that numerous products could become unavailable and estimated significant loss of inventory if required to implement the labeling change by April 23, 1999.

One comment requested permission to use up all existing supplies of labeling that contain the precise alcohol warning contained in an agency letter dated March 14, 1996 (Ref. 3). Another comment, submitted by a manufacturer, stated that it would implement the new alcohol warnings by the effective date and that other affected companies should also be required to meet that date (Ref. 4).

The agency held a public meeting on January 20, 1999 (Ref. 5), to hear the views of interested parties regarding the implementation date of the rule. At this meeting, one large private label manufacturer of internal analgesic/antipyretic drug products stated that it would not be able to meet the April 23, 1999, implementation date, and that if the deadline were not extended a real possibility existed that there would be a national shortage of certain products that it manufactures. Another manufacturer at the meeting stated that it would be able to comply by the implementation date.

### **III. The Agency's Response**

As stated in the final rule, the agency considers the lack of sufficient alcohol warnings to be a significant public health issue. However, additional information (Refs. 6 through 11) that the agency has obtained since publication of the final rule suggests that the agency may have

underestimated the number of individual label changes that some manufacturers will have to make. This information also indicates that there may be a significantly greater disparity in the effect of the required labeling upon manufacturers than originally anticipated. For these reasons, FDA now believes that the original 6-month implementation period would not provide adequate time for many manufacturers of affected products to relabel a significant number of their products and that strict adherence to the April 23, 1999, effective date might result in short-term shortages of some of these important OTC drug products, which are widely used by many consumers. Consequently, the agency believes that establishing a compliance date for the regulation, until October 22, 1999, will provide sufficient time for industry to implement the labeling revisions required for these OTC internal analgesic/antipyretic drug products.

The agency does not believe that there should be an open-ended period, as one comment requested, to use up existing supplies of labeling that contain an alcohol warning that was implemented voluntarily in response to an agency letter dated March 14, 1996 (Ref. 3). Rather, FDA believes that there should be a date certain after which all products initially introduced or initially delivered for introduction into interstate commerce contain the new warnings. Further, because of the importance of the alcohol warnings, the agency continues to encourage all affected manufacturers to bring their labeling into compliance with the final rule as promptly as possible.

Because this document merely establishes a compliance date, FDA finds that notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 553(b) and (d)). Moreover, because of the need for the agency to publish this document before the original April 23, 1999, effective date, notice and comment **rulemaking** would be impracticable for this document.

#### **IV. Analysis of Impacts**

The economic impact of the final regulation was discussed in the final rule (63 FR 56789 at 56798 to 56799). This document will provide additional time for companies to relabel affected products and will reduce label obsolescence, as there will be additional time to use up more existing

labeling. Thus, setting a compliance date of October 22, 1999, should reduce the economic impact on industry significantly.

FDA has examined the impacts of this final rule (establishment of the compliance date) under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles set out in the Executive Order. 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 Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule sets a compliance date, which will provide manufacturers additional time to use up existing product labeling. Accordingly, the agency certifies that the 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.

## **V. Paperwork Reduction Act of 1995**

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

## VI. Environmental Impact

The agency has determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VII. References

The following references are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rrm. 1061, Rockville, MD 20852, and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment Nos. C20, C21, and C22, Docket No. **77N-094W**, Dockets Management Branch.
2. Comment No. CP 1, Docket No. 77 N-094W, Dockets Management Branch.
3. Letter from D. Bowen, FDA, to R. Soiler, Nonprescription Drug Manufacturers Association, Coded LET2, Docket No. 77N-094W, Dockets Management Branch.
4. Comment No. C19, Docket No. 77N-094W, Dockets Management Branch.
5. Comment No. MM, Docket No. 77N-094W, Dockets Management Branch.
6. Letter from K. Rothschild, FDA, to D. Jespersen, Perrigo, coded LET3, Docket No. 77N-094W, Dockets Management Branch.

7. Letter from K. Rothschild, FDA, to H. McCain, Whitehall-Robins, coded LET4, Docket No. 77 N-094W, Dockets Management Branch.

8. Comment No. C23, Docket No. 77 N-094W, Dockets Management Branch.

9. Comment No. C24, Docket No. 77N-094W, Dockets Management Branch.

10. Letter from K. Rothschild, FDA, to H. McCain, Whitehall-Robins, coded LETS, Docket No. 77N-094W, Dockets Management Branch.

11. Comment No. C25, Docket No. 77N-094W, Dockets Management Branch.

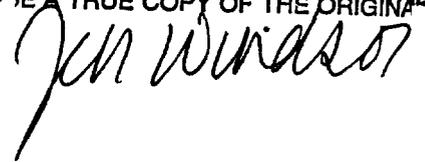
Dated: 3/11/99  
March '11, 1999



---

William K. Hubbard  
Acting Deputy Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**