administrative record, and shall not consider data or information not included as part of the administrative record.

(iii) The administrative record shall consist solely of the following material: All notices and orders published in the **Federal Register**, all data and views submitted in response to the request published pursuant to paragrah (a)(2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section, all minutes of panel meetings, the panel report(s), all comments and rebuttal comments submitted on the proposed monograph and all new data and information submitted pursuant to paragraph (a)(6) of this section, all objections submitted on the tentative final monograph and all new data and information and comments submitted pursuant to paragraph (a)(7) of this section, the complete record of any oral public hearing conducted pursuant to paragraph (a)(8) of this section, all other comments requested at any time by the Commissioner, all data and information for which the Commissioner has reopened the administrative record, and all other material that the Commissioner includes in the administrative record as part of the basis for the Commissioner's decision.

* * * * *

(12) *Amendment of monographs.* (i) The Commissioner may propose on the Commissioner's own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal pursuant to § 10.30 of this chapter. The Commissioner may deny the petition if the Commissioner finds a lack of safety or effectiveness employing the standards in paragraph (a)(4) of this section (in which case the appeal provisions of paragraph (a)(11) of this section shall apply), or the Commissioner may publish a proposed amendment or repeal in the **Federal Register** if the Commissioner finds general recognition of safety and effectiveness employing the standards in paragraph (a)(4) of this section. Any interested person may, within 60 days after publication of the proposed order in the **Federal Register**, file with the Dockets Management Branch, Food and Drug Administration, written comments in quadruplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed in the Dockets Management Branch between the hours of 9 a.m. and 4 p.m., Monday through Friday. After reviewing the comments, the Commissioner shall publish a final order amending the monograph established under the provisions of paragraph (a)(9) of this section or withdraw the proposal if comments opposing the amendment are persuasive. A new drug application may be submitted in lieu of, or in addition to, a petition under this paragraph.

(ii) A new drug application may be submitted in lieu of a petition to amend the OTC drug monograh only if the drug product with the condition that is the subject of the new drug application has not been marketed on an interim basis (such as under the provisions of paragraph (a)(6)(iii) of this section), all clinical testing has been conducted pursuant to a new drug application plan, and no marketing of the product with the condition for which approval is sought is undertaken prior to approval of the new drug application. The Food and Drug Administration shall handle a new drug application as a petition for amendment of a monograph, and shall review it on that basis, if the provisions of this paragraph preclude approval of a new drug application but permit the granting of such a petition.

* * * * *

Effective date. This regulation shall be effective November 30, 1981.

(Secs. 201, 502, 505, 701(a), 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055 (21 U.S.C. 321, 352, 355, 371(a)))

Dated: July 7, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: September 8, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 81-28168 Filed 9-28-81; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N-0295]

Over-the-Counter (OTC) Drug Review Policy Statement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces the policy the agency intends to use concerning: (1) the submission and review of proposed protocols to evaluate an ingredient or condition in the over-the-counter (OTC) drug review, (2) meetings with industry or other interested persons, (3) communications by the agency on submissions of test data and other information, and (4) maintenance of a public record involving these activities.

DATE: Comments by November 30, 1981.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule revising the procedural regulations in 21 CFR 330.10 for revising and classifying OTC drugs to delete the provision that authorizes the marketing of a Category III ingredient or other condition in an OTC drug product after a final monograph is established. This action is being taken to conform to the holding and order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). this revision in the regulations will affect the time period during which new data may be submitted to FDA to support the inclusion in a final monograph of a condition not classified in Category I in a proposed or tentative final monograph.

When FDA issued the OTC drug review regulations in 1972, it concluded that Category III testing should not be required until after publication of the applicable final monograph. Because of the court decision in *Cutler* v. *Kennedy, supra,* any testing necessary to resolve the issues that resulted in a condition not being classified in Category I, and submission of the test data or other available data to FDA to support inclusion of the condition in a final monograph, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Under the current OTC drug review procedures, new data may be submitted as part of the comments to a panel report and proposed monograph. After the administrative record has closed, new data or information not previously submitted for inclusion in the administrative record may be submitted for inclusion only with a petition to the Commissioner requesting that the administrative record be reopened to include such material. In the past, such data and information received prior to the publication of a tentative final or final order have been addressed in he appropriate order.

Under the new procedures described in the final rule published elsewhere in this issue of the **Federal Register**, the agency's decision contained in a tentative final monograph will be based solely on the administrative record developed through the 90-day comment and 30-day rebuttal comment period following the proposed monograph. New data and information may be submitted after the 90-day comment period, but will be considered only after the administrative record is reopened following publication of a tentative final monograph. After publishing the tentative final monograph, FDA will reopen the administrative record for 12 months to permit interested persons to submit new data and information in support of the safety and effectiveness of any condition reviewed by a panel and not classified by the agency in Category I. Following a 2-month rebuttal comment period, the administrative record will be closed, and the agency's decision on the conditions to be included in a final monograph will be based solely on the administrative record developed throughout the entire OTC rulemaking period. Any data received by FDA after closing of the administrative record following the tentative final monograph will ordinarily be handled after publication of the final monograph as a petition to amend the monograph, unless the Commissioner finds that good cause has been shown that warrants earlier consideration.

While manufacturers have not been required under current regulations to conduct Category III testing until after completion of the OTC drug administrative procedures, i.e., publication of the final monograph, some firms have conducted such testing during the course of the review and have submitted the data as comments to a published panel report and proposed monograph or as a petition after the comment/reply comment period for the proposed monograph had closed. In the past, such testing did not have to be conducted until a final monograph had been published, and FDA did not comment on the results of this testing until a tentative final monograph was published. Likewise, data were sometimes submitted after a tentative final monograph was published, and FDA did not comment on these data until a final monograph was published. Although, in some instances, FDA may have completed its review of data at an early date, the agency's evaluation of that data would not be made public until the agency had completed its review of all data in the administrative record and had published its conclusions in either a tentative final or final monograph.

Under the revised OTC procedural regulations, all Category III testing must be completed prior to publication of a final monograph, if a manufacturer is interested in upgrading a condition to Category I status before the establishment of a final monograph. Because of the importance of early testing under the new procedures, manufacturers wish to be informed of the status of data previsouly submitted before initiating further studies. Providing this information to interested persons as the agency's reviews of these data are completed should result in earlier testing, where necessary, and the submission of the results earlier to FDA. To the extent possible, the agency plans to inform manufacturers of any tentative determination it has reached that additional data are needed or that the data sumitted are adequate to establish Category I status so that further testing appears unnecessary. Announcing these decisions early in the process will also benefit consumers because additional testing will be encouraged when it is needed, and consumers will know at an earlier date what ingredients have been tentatively recommended for upgrading to Category I status.

FDA staff will also meet with manufacturers, as necessary and as agency resources permit, to discuss testing protocols. FDA hopes to provide this information at an early enough date so that manufacturers can complete any additional necessary studies and can submit the data in the most expeditious fashion possible. Manufacturers should be aware though that their obligation to submit the data necessary to support the movement of a Category III condition to Cateogry I is independent of any information provided by the agency.

Similarly, the agency will not delay the OTC drug review in order to provide this "feedback," but will proceed to the next appropriate publication as soon as it is possible to do so under the procedures detailed in the revised OTC drug procedural regulations published elsewhere in this issue of the **Federal Register.**

FDA will meet with industry representatives at their request to provide information on data already submitted to FDA, to consult on testing guidelines for those conditions which industry is interested in upgrading, and to advise industry on the adequacy of their proposed testing protocols. Any communications between the agency and industry on these matters may continue outside the formal comment periods and will be part of the public record.

Further details are described below.

Protocols and Test Data

All proposed testing protocols and test data will be part of the public record and should be submitted in four copies to the Dockets Management Branch, FDA (address above), in accordance with the OTC drug review administrative procedures in § 330.10. All submissions should make reference to the appropriate docket number. Copies of any acceptable protocols or testing guidelines will also be placed in the Dockets Management Branch under the appropriate docket numbers. Any information that the agency provides sponsors on these test data and protocols will also be publicly available and will be placed in the Dockets Management Branch.

Meetings

Any person wishing to meet with agency representatives to discuss a proposed protocol or data previously submitted to the agency may request such a meeting by contacting the Division of OTC Drug Evaluation (HFD–510) (address and phone number provided above), which is responsible for coordinating all meetings. All such meetings will be open to the public.

Whenever an agency employee meets with a firm, an individual, or group of persons and discusses testing protocols, or data previously submitted to the agency, the FDA employee will make a memorandum of that meeting and the memorandum will be placed in the Dockets Management Branch under the appropriate docket number.

Communications on Submitted Data

Communications to manufacturers concerning submitted data will be of two types. First, as the Bureau of Drugs (Bureau) reviews the data, staff members may find it necessary to request clarification of certain points or to request additional data from the sponsor. The agency employee may request the information by letter or by telephone. A copy of the letter to the manufacturer that submitted the data or a copy of a memorandum of telephone conversation will be placed in the Dockets Management Branch under the appropriate docket number. All data submitted in response to FDA's request for additional information must be submitted to the Dockets Management Branch.

Second, when the Bureau completes its review, it will make a tentative determination that the data submitted are or are not adequate to support a Category I status for the condition. Whenever possible, the Bureau plans to notify the sponsor that the data are inadequate or that it has made a tentative interim decision to recommend to the Commissioner that the condition be upgraded in the next publication of the monograph (tentative final or final monograph) so that further expenses of testing can be eliminated. A copy of the letter informing the manufacturer of the tentative interim decision will also be placed in the Dockets Management Branch so that all other interested manufacturers and consumers will be informed. The agency points out that the Bureau's decision to recommend upgrading of the condition to Category I is only tentative and could change at the time the tentative final or final monograph is published if new information becomes available or if the Commissioner does not accept the Bureau's recommendation. Manufacturers acting in reliance upon this tentative interim decision must act at their own risk.

Public Record

The Bureau of Drug's Division of OTC Drug Evaluation intends to make available in the Dockets Management Branch under Docket Number 80N–0295 a record of information provided to manufacturers so that the interested persons can be aware of all communications that the Bureau has made concerning any Category II or III conditions. Each month the Division of OTC Drug Evaluation will update the list which will itemize each letter, meeting, and protocol, providing the date of the item, the persons involved, and the docket number under which the detailed information may be found. Interested persons are advised to check the Dockets Management Branch routinely to keep informed.

It is important to note the impact of this policy regarding FDA review of data and information and consultation on protocols or testing guidelines. Under this policy a substantial number of communications between FDA and interested persons on the subject of Category III testing will occur and will become a part of the public record. These communications will not be included in the administrative record for the related OTC monograph unless the communication directly influences an agency decision on a particular matter in the monograph or provides the substantiation for the agency's decision on that matter. For example, a protocol or test guideline would not normally become part of the administrative record, but the results of the study, which may also be the subject of one of these communications, would be included in the administrative record because it would be one of the bases for the Commissioner's final decision on the ingredient.

Notice and comment is not necessary before issuing this policy statement. (See 5 U.S.C. 553(b)(B).) Furthermore, the purpose and major aspects of this policy statement were described in the preamble to the May 13, 1980, proposed rule (45 FR 31422) on the agency's Category III regulations for which a final rule is published elsewhere in this issue of the **Federal Register.** It would also be contrary to the public interest to delay implementing the policy described in this policy statement.

Interested persons may, on or before November 30, 1981, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this policy statement. 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. Such comments will be considered in determining whether amendments or revisions to the policy statement are warranted. Received comments will be incorporated into the public file on the statement and may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 7, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: September 8, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 81-28108 Filed 9-28-81; 8:45 am]

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federal register

Tuesday
September 29, 1981

Part V

Architectural and Transportation Barriers Compliance Board

Minimum Guidelines and Requirements for Accessible Design; Proposed Regulations; Extension of Comment Period

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1190

[ATBCB Docket No. 81-G-1]

Minimum Guidelines and Requirements for Accessible Design; Extension of Comment Period

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Extension of comment period on proposed rule.

SUMMARY: On August 4, 1981, the Architectural and Transportation Barriers Compliance Board (ATBCB or the Board) published in the Federal Register a notice of proposed rescission of the Board's minimum guidelines and requirements for standards for accessibility and usability of federal and federally-funded buildings adopted on January 6, 1981. Several individuals and organizations have requested additional time for the submission of comments. In order to provide additional time for comment, the period for comment is extended to November 6, 1981.

DATE: Comments must be postmarked on or before November 6, 1981.

ADDRESSES: Send comments to: Charles D. Goldman, General Counsel, Rulemaking Docket 81-G-1, Architectural and Transportation Barriers Compliance Board, Room 1010, 330 C Street, SW., Washington, D.C. 20202-2101. Comments received will be available for public inspection in Room 1014 from 9 a.m. to 5:30 p.m., Monday through Friday. Copies of this notice are available on tape for those with visual impairments. These may be obtained at the above address.

FOR FURTHER INFORMATION CONTACT: For additional copies of this notice of extension, of the notice of proposed rulemaking published on August 4, 1981 (46 FR 39764), and of the ATBCB Minimum Guidelines and Requirements for Accessible Design (36 CFR Part 1190), contact Mr. Larry Allison, Director, Office of Public Information, (202) 245-1591 (voice or TDD), 330 C Street, SW., Room 1010, Washington, D.C. 20202-2101.

For information on the applicability, scoping and technical provisions of the Board's Minimum Guidelines and Requirements for Accessible Design (36 CFR Part 1190) and for information on questions contained in this notice of extension, contact Ms. Sally Free, Office of Technical Services, (202) 472-2700 (voice), 330 C Street, SW., Room, G-115D, Washington, D.C. 20202-2101, or Mr. Charles D. Goldman, General Counsel (202) 245-1801 (voice or TDD), 330 C Street, SW., Room 1010, Washington, D.C. 20202-2101.

SUPPLEMENTARY INFORMATION: The Architectural and Transportation Barriers Compliance Board has identified portions of its January, 1981, regulation, Minimum Guidelines and Requirements for Accessible Design (36 CFR Part 1190) on which specific comments are requested. Such items include parking and passenger loading zones, entrances, elevators, toilet and bathing facilities, alarms, listening systems, additions, alterations, leases, special use facilities, and residential structures.

The Board emphasizes that it seeks public comments on all parts of the Guidelines and Requirements and specifically seeks comments on which sections of this regulation should be retained, which sections should be modified and which sections should be reserved. The Board also seeks comments on the clarity and format of the regulation.

The Architectural Barriers Act requires that buildings and facilities be "readily accessible" 42 U.S.C. 4155. Ready access is a high standard, more than "reasonable access." Some Board members are concerned that some requirements contained in the ATBCB Minimum Guidelines and Requirements for Accessible Design are too onerous, while others feel that some requirements do not go far enough.

The Board would welcome comments on the subject of the degree of specificity in the Minimum Guidelines and Requirements and any legal implications in the approaches taken by the Board. The Board is also interested in comments on whether it has provided sufficient access, to much access, or not enough access, and what, if any, appropriate modification(s) might be made.

The ATBCB is concerned that its Minimum Guidelines and Requirements provide ready access and use to federal and federally funded buildings in a cost effective manner. The Board seeks information on which sections of the regulation produce a cost savings, which create additional costs, and which have no cost impact. Comments are sought as to the extent to which cost should be considered in providing access to federal and federally funded buildings and facilities. The public is invited to submit alternatives to current requirements which might provide ready access and use in a more cost effective manner.

The Board requests that comments submitted in response to this notice include citations to any background materials, source documents, personal or field experience, cost data, and other information providing a basis for the response. The section numbers and paragraph letters cited in the questions contained in this notice correspond to the particular section/paragraph addressing that subject in the guidelines and requirements.

1. § 1190.31(b) Parking and passenger loading zones. The following table included in the Minimum Guidelines and Requirements applies to both visitor and employee parking. Are any changes necessary—for example, should the number of required accessible spaces be increased, decreased, or remain the same?

Total parking in lot	Required minimum number of accessible spaces
1 to 25	1
26 to 50	2
51 to 75	3
76 to 100	4
101 to 150	5
151 to 200	6
201 to 300	7
301 to 400	8
401 to 500	9
501 to 1,000	(1)
Over 1,000	(2)

[1] 2 percent of total.
[2] 20 plus 1 for each 100 over 1,000.

2. § 1190.31(h) Entrances. The Board's Minimum Guidelines and Requirements provide that when a new building or facility is designed and constructed having entrances which normally serve transportation facilities, passenger loading zones, parking facilities, taxi stands, public streets, interior vertical access, and different sides of the facility, that at least one entrance serving each such function shall be accessible. Should the number of accessible entrances be increased, decreased, or remain the same?

3. § 1190.31(f) Elevators. In new construction, the ATBCB Minimum Guidelines and Requirements provide that all levels or floors of a building or facility be accessible and that each elevator serving those floors or levels be accessible. The Board seeks additional comments on the number of elevators in a new building that should be accessible; the distance between elevator banks containing the accessible elevators(s) if all elevators in the building are not accessible; and any problems/benefits which may result if all elevators are not accessible. The Board also would welcome cost information attributable directly to the

installation and maintenance of a mass produced accessible elevator which would otherwise not be incurred by an inaccessible model.

4. § 1190.31(k) Toilets and bathing facilities. For new construction, the ATBCB Guidelines and Requirements provide that at least one accessible fixture and accessory (*e.g.*, water closet, lavatory) in each toilet room be accessible. Should more than one accessible fixture be provided in each toilet room? Concern has been expressed that additional square footage may be required in some toilet rooms to make them accessible and this could result in additional costs. Comments addressing this concern would be helpful. In addition, should the Board provide that a certain number or percentage of the toilet rooms be accessible, and, if so should a maximum distance between such accessible toilet rooms be established? Should certain types of facilities be exempt from these requirements?

5. § 1190.31(n) and 1190.180 Alarms. The guidelines and requirements provide that if an audible alarm is provided in new construction, then a visual alarm device shall also be used. The Board seeks advice on other methods to alert physically handicapped persons in an emergency. For example, where is the best location to install a visual alarm system? Should an occupant emergency organization plan be permissible as an alternative? Once special devices are approved for use, should they be required to go through case-by-case approvals?

6. § 1190.32 Additions. Section 1190.32 requires that if an addition is made to a facility, either the addition or the existing structure must provide an accessible entrance and accessible route so that the addition is accessible and usable by handicapped persons. Such a requirement may sometimes necessitate alteration of parts of an existing structure. Should the regulation continue to require an accessible route to the new addition even if such access would necessitate alteration of the original structure; or should an accessible route be provided only if and when the existing structure is altered at a later date; or should the existing structure be altered in its entirety at the time the addition is made so that the entire facility is totally accessible?

7. § 1190.33(a)(2) Vertical Access. The ATBCB Minimum Guidelines and Requirements provides that an alteration of stairs and escalators is to be treated as an alteration of the building's system for vertical access so that accessibility is provided to all levels of a building or facility. The Board seeks recommendations on whether this provision should apply to all facilities or if some facilities should have special requirements developed to meet their particular needs. If so, please indicate the type of facility and the basis of the response.

8. § 1190.33(a)(3) Alteration of a single element. Section 1190.33(a)(3) provides that if alterations of single elements, when considered together, amount to an alteration of a space of a building or facility, the space shall be made accessible. For example, if a water closet and lavatory are altered in a toilet room, under current requirements, the toilet room itself would probably be required to be altered to make the toilet room accessible. The Board requests public comment on the appropriateness of this provision as it now exists or whether it should be clarified or modified.

9. § 1190.33(b) Fifty percent rule. Section 1190.33(b) requires that if the total cost of all alterations for a building or facility within any twelve month period is 50 percent or more of the building's value, then the altered building is required to meet certain basic accessibility requirements—that is, at least one accessible route, and at least one accessible toilet facility on each substantially altered floor with a minimum of one accessible toilet facility in each altered building must be provided. Should such a percentage of the building's value be used to trigger basic accessibility requirements and, if so, should this percentage be larger, smaller, or the same percentage of the building's value contained in the present requirements? Is an alteration that costs 50 percent or more of the building's whole value sufficient to consider the altered building as "new construction" and thus necessitate additional alterations to the existing structure? Should criteria other than a percentage of the cost of alterations to the building's value be used to trigger additional accessibility requirements?

10. § 1190.34 Leases. Are the present requirements contained in § 1190.34 Leases sufficient or should modification in this section be considered? For example, should additional factors, such as usage classification, square footage of the facility, size of the population to be served, or other similar criteria be used in determining the applicability of the leasing provisions?

11. Subpart E—Special Building or Facility Types or Elements. The Guidelines and Requirements as issued in January, 1981, may in the future provide the basis for special use requirements which will then be applicable to the development of standards for special use buildings and facilities issued under the Architectural Barriers Act. Particularly with alterations, in certain types of structures, such as historic buildings, transit stations, schools, and hospitals, achieving ready access may necessitate greater creativity from both an engineering and financial perspective. The Minimum Guidelines and Requirements apply to the generic or common features of a structure. Subpart E when developed should contain provisions applicable for unique features of special use buildings. Are there particular building types that need special treatment? Commenters are encouraged to share their views on the current ATBCB approach and suggest alternatives.

12. Residential Structures. Agency provided information indicates barrier free residential structures for federally constructed and funded public housing can be expensive, particularly in multi-unit facilities or special types, such as townhouses or garden apartments. Should the current ABCB Minimum Guidelines and Requirements apply to the common or public areas of the facility, such as lobbies, recreational facilities and laundries? Should they apply to all units, a percentage of the units, or not at all to publically funded residential structures? Are there special types of such residential structures where only one level of units should be accessible?

Dated: September 22, 1981.

By vote of the Board.

Mason H. Rose,

Chairperson, Architectural and Transportation Barriers Compliance Board.

Wm. Bradford Reynolds,

Vice Chairperson, Architectural and Transportation Barriers Compliance Board.

[FR Doc. 81-28322 Filed 9-28-81; 8:45 am]

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