DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 330]

CLASSIFICATION OF OVER-THE-COUNTER (OTC) DRUGS

Proposal To Designate the Contents and the Time of Closing of the Administrative Record

In the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), the Commissioner of Food and Drugs promulgated procedures governing the review and classification of over-the-counter (OTC) drug products. Questions have recently been raised about the contents of the administrative record on the basis of which the decision is made with respect to the status of an OTC drug product pursuant to these procedures, and the point beyond which new factual information may no longer be submitted for consideration in the administrative process. The Commissioner has concluded that it is appropriate to publish a proposal to add provisions to the regulations to settle these matters.

THE CONTENTS OF THE ADMINISTRATIVE RECORD

Comments filed on the proposed OTC drug review procedures, published in the FEDERAL REGISTER of January 5, 1972 (37 FR 85) had suggested that the final regulation should designate the administrative record on which the administrative decision would be based, for purposes of court appeal. The Commissioner responded in paragraph 82 of the preamble to the final regulation (37 FR 9471) that:

> The record for any court appeal will include all pertinent documentation of the proceeding, including the panel report(s), summary minutes, proposed monograph, tentative final monograph, transcript of oral hearing, final monograph, all comments or objections filed with the Hearing Clerk on the proposed and tentative final monographs, and all data and information received by the panel and made publicly available through the Hearing Clerk. The record for appeal will be compiled by the Office of General Counsel. There is no need to specify these details in the regulations.

A comment on the proposal had also requested that a full transcript of each panel meeting be made public, which presumably would then have been a part of the administrative record. The Commissioner responded to this comment in paragraph 37 of the preamble to the final regulation, stating that a verbatim transcript of all panel meetings would not be necessary in view of the extensive procedural safeguards set out in the regulation and the fact that the OTC drug panels only report recommendations to the Commissioner, who must then make the final decisions after full public procedure.

Thus, the preamble to the final OTC drug review procedural regulations explicitly designated the contents of the administrative record and excluded any transcript that may be made of any panel meeting.

The Commissioner published in the FEDERAL REGISTER of January 8, 1974 (39 FR 1359) a notice of a public hearing to be held on the tentative final order for OTC antacid drug products, pursuant to the provisions of § 330.10(a)(8) (formerly § 130.391(a)(8)) of the regulations. The notice reiterated the content of the administrative record as designated in the preamble to the final order establishing the procedural regulations for the OTC drug review.

In response to this notice, an objection was received on the designation of the administrative record. The objection contended that the complete transcript of the meetings of the Panel should be included as part of the administrative record. The Food and Drug Administration replied that such transcripts are exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(5), and that in any event they are not considered by the Commissioner in the formulation of his decisions and orders and thus do not properly constitute part of the administrative record. The Food and Drug Administration stated that, in order to avoid any possible confusion on this matter, the procedural regulations would be amended explicitly to state this fact.

The Commissioner is obligated to base his decision with respect to a monograph on the entire administrative record. In the case of the final antacid monograph, which is published elsewhere in this issue of the FEDERAL REGISTER, the Commissioner has not at any time read or referred to or relied upon the words recorded in the transcripts of the Antacid Panel meetings. Rather, he has relied solely upon the minutes of the Panel meetings, the data and information submitted to and considered by the Panel, the Panel report, the comments submitted on that report, the tentative final order, the objections submitted on the tentative final order, the transcript of and material submitted at the public hearing, and comments permitted to be filed subsequent to the public hearing. This constitutes the administrative record specified in the notice of May 11, 1972, and is the sole basis on which the proposal, the tentative final order, and the final order were made by the Commissioner. The Commissioner has concluded that the same procedure will be followed for his consideration of future OTC drug monographs.

The irrelevance of the transcripts of the panel deliberations can perhaps best be described by an analogy. The transcripts reflect deliberations and debates among a group of individuals prior to arriving at a final recommendation. The group, in this instance, is deliberating upon recommendations with respect to regulatory policy that will ultimately have the force and effect of law. Their deliberations are therefore directly analogous to the deliberations of a panel of judges of a United States Court of Appeals. It is obvious that the judges who hear a case deliberate among themselves with respect to the issues involved. Moreover, it would not be unusual that there will be several drafts of an opinion, and that the final decision might be quite different from the initial discussions or even tentative drafts. The final opinion written by the court, however, is the only document appealable to or reviewed by the United States Supreme Court. The deliberations of the Court of Appeals, and their various drafts reflecting intermediate considerations and positions, are not a part of the record and are not reviewed by the Supreme Court. The final opinion must stand or fall on its own merits. The same is true of the final reports of the OTC drug review panels. They stand or fall on their own merits, and are either supported or unsupported by the medical and scientific evidence submitted to and considered by the panel.

The logic of this position is further compelled by the fact that not all panel deliberations are recorded or transcribed. Although some transcription or recording occurs with most of the OTC drug review panels, it is necessarily incomplete. Panel members frequently confer by telephone with each other, discuss matters over lunch and dinner, and talk about them during breaks and in the corridors. Moreover, the major reflective consideration of the issues involved would be likely to occur before and after meetings, when the panel members individually review the data and information and form their conclusions with respect to it. Thus, any transcript of panel deliberations would reflect only a part, and perhaps a small part, of the consideration given to the matter, of the reasoning which lies behind the recommendations ultimately made, and thus of the entire deliberative process. It would therefore be highly improper to consider the transcripts of panel meetings in determining the validity of the final OTC antacid drug monograph.

Moreover, the purely deliberative portions of a panel's discussion during which it formulates its conclusions and recommendations are lawfully closed to the public and any transcripts relating to this portion of the meetings are therefore properly retained as confidential under 5 U.S.C. 552(b)(5) rather than as part of the public administrative record.

The legal justification for closing the deliberative portion of a panel's discussions, i.e., the discussion during which the panel determines its conclusions and recommendation—and retaining the transcripts of those closed portions as confidential may be found in section 10 of the Federal Advisory Committee Act and exemption (5) of the Freedom of Information Act. Section 10(a)(1) of the Federal Advisory Committee Act provides that each advisory committee meeting shall be open to the public. Section 10(d) then provides that paragraph (a)(1) shall not apply to any advisory committee meeting which the head of the agency determines is concerned with matters listed in 5 U.S.C. 552(b), and requires that any such determination shall be in writing and shall contain the reasons therefor.

The authority to close the Food and Drug Administration advisory committee meetings has been delegated to the Commissioner, subject to the concurrence of the office of General Counsel. 21 CFR 2.120(a)(18). In exercising his authority to close portions of advisory committee meetings pursuant to this delegation, the Commissioner has acted on the basis of the guidelines established by the Office of Management and Budget and the Department of Justice as set out in the FEDERAL REGISTER of January 23, 1973 (38 FR 2306). The Commissioner's formal written determination to close a portion of a meeting is published together with the notice of the meeting in the FEDERAL REGISTER.

The basis on which the purely deliberative portions of panel discussions have been closed pursuant to section 10 (d) of the Federal Advisory Committee Act is that the discussions are concerned with matters covered by 5 U.S.C. 552(b)(5), i.e., internal communications. As the Attorney General's Memorandum of June 1967 on this portion of the Freedom of Information Act states:

> * * * internal communications which would not routinely be available to a party in litigation with the agency, such as internal drafts, memoranda between officials or agencies, opinions and interpretations prepared by agency staff personnel or consultants for the use of the agency, and records of the deliberations of the agency or staff groups, remain exempt so that free exchange of ideas will not be inhibited. As the President stated upon signing the new law, "officials within the government must be able to communicate with one another fully and frankly without publicity.

All of the panel members are, of course, consultants to the Food and Drug Administration and, as such, government employees during their period of actual work on the panel. The discussion within a panel therefore stands on no different footing than a discussion within an internal Food and Drug Administration staff meeting.

At the same time, the Commissioner recognizes that, consistent with the Federal Advisory Committee Act, advisory committee proceedings should remain open to public view and include participation to the maximum extent feasible. It is for this reason that all interested persons are provided an opportunity to make written submissions to each panel and to present oral views to the panel. The Commissioner has concluded, however, that the deliberations of the panels during which their conclusions and recommendations are determined could not reasonably be made in open session, and thus that it is essential to avoid undue interference with the regulatory process that they be closed to the public.

The primary reason for closing such deliberative portions of advisory committee meetings is, of course, because of the regulatory nature of the action being considered. With respect to the OTC drug review, the issues involve the possibility of specific law enforcement action against an individual product, e.g., requiring relabeling of the drug or new testing by the manufacturer, or removing the product from the market completely. The panel discussions include a continuous admixture of deliberations on interim regulatory decisions, and thus much of the panel discussion is closed to protect the integrity of the regulatory process.

Accordingly, the Commissioner proposes to amend § 330.10 to designate the contents of the administrative record upon which his decision on a monograph shall be based, and to exclude the transcripts of any panel meetings from that designation. The decision will be required to be based solely upon the administrative record so designated and not upon any data, information, or materials not included as part of such record. Court appeal will then be based solely upon that record and the information it contains.

CLOSING OF THE ADMINISTRATIVE RECORD

The notice published in the FEDERAL REGISTER of January 8, 1974 (39 FR 1359) announcing the public hearing on the tentative final order for OTC antacid drug products also stated that, since this was a hearing on the administrative record, only data and information submitted at an earlier stage in the proceeding would be considered. The notice stated that any new data or information could be discussed only if such material were first submitted to the Commissioner with a petition to reopen the administrative record to include such new material, justifying why it was not submitted earlier, and the Commissioner granted the petition.

One objection was received to this notice, contending that this requirement was not included in § 330.10 (formerly § 130.301) of the regulations. In reply, the Food and Drug Administration stated that, although it believed that the procedural regulations made it clear that new evidence could not for the first time be submitted at the public hearing on the tentative final order, such evidence would be accepted as an exception on that occasion and that the procedural regulations would then be amended to prevent recurrence of this problem in the future.

It is standard procedural practice before all administrative bodies and courts that the record in any proceeding is closed at some specified point in time to prevent continuous submission of new data and information. Thereafter in the proceeding, arguments and contentions may be made solely on the basis of the data and information already contained in the record, and new data or information can be filed only with the permission of the presiding officer upon sound justification why the material was not submitted earlier.

The Commissioner concludes that, in the OTC drug review, submission of new data and information should be permitted only through the 60-day period permitted under § 330.10(a)(6) (formerly § 130.301(a)(6)) for comment on the proposed monograph. Thereafter, all rebuttal comments, objections, and statements at the oral hearing must be based solely upon the administrative record developed through that time. Permission to submit additional data or information may be granted, in the sole discretion of the Commissioner, on the basis of a petition to reopen the administrative record to include such material. Any such petition shall demonstrate good cause why such material could not have been obtained and submitted in response to the initial call for data and information or as part of the comments on the proposed monograph. If such a petition is not granted, such material is properly submitted with a subsequent petition to amend the monograph.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1050–53 as amended, 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended; (5 U.S.C. 553, 702, 703, 704)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend 21 CFR Part 330 by redesignating § 330.10(a) (10) through (13) as (a) (11) through (14) and by adding a new § 330.10(a)(10) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

* * * * * *

(a) * * *

(10) *Administrative record.* (i) All data and information to be considered in any proceeding pursuant to this section shall be submitted in response to the request for data and views pursuant to paragraph (a)(2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section or submitted to the Hearing Clerk as part of the comments during the 60-day period permitted pursuant to paragraph (a)(6) of this section. Thereafter, no new data or information may be submitted for inclusion in the administrative record of such proceeding except as provided in paragraph (a)(10)(ii) of this section.

(ii) New data or information not previously submitted for inclusion in the administrative record may be submitted for such inclusion only with a petition to the Commissioner requesting that the administrative record be reopened to include such material. The Commissioner may grant or deny such petition in his discretion. Any such petition shall demonstrate good cause why such material could not be obtained and submitted within the time specified in paragraph (a)(10)(i) of this section. If such a petition is denied, such material is properly submitted with a petition to amend the monograph pursuant to paragraph (a)(12) of this section.

(iii) The Commissioner shall make all decisions and issue all orders pursuant to this section solely on the basis of the

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

(iv) 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 paragraph (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 pursuant to paragraph (a)(6) of this section, all objections submitted on the tentative final monograph 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 which the Commissioner includes in the administrative record as part of the basis for his decision.

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Interested persons may, on or before July 5, 1974 file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: May 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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[21 CFR Part 330]

OTC DRUGS

Proposed General Conditions

In the FEDERAL REGISTER of November 12, 1973 (38 FR 31258) the Commissioner of Food and Drugs promulgated general conditions for OTC drugs that are generally recognized as safe and effective and are not misbranded. Section 330.1(g) (formerly § 130.302(g)) included a general warning: "Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a physician immediately." Section 330.1(i) (formerly § 130.302(i)) included the following drug interaction warning: "Warning: Do not take this product concurrently with a prescription drug except on the advice of a physician." The effective date of that order was December 12, 1973.

A number of written comments were received in response to that order. The Commisisoner also entertained comments on § 330.1 (g) and (i) and related issues at the public hearing that was held on January 21, 1974, pursuant to the notice published in the FEDERAL REGISTER of January 8, 1974 (39 FR 1359). In view of these written and oral comments, the Commissioner has concluded to reopen this matter and to propose a new version of the general warning in § 330.1(g) and to revoke the drug interaction warning in § 330.1(i).

There was comment that the words "consult your poison control center" should be added to the general warning under § 330.1(g) (formerly § 130.302(g)).

The Commissioner concurs that it would be in the best interest of the consumer to have knowledge that there is more than one source of professional assistance available. For that reason the Commissioner proposes to amend the statement to read: "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact your poison control center immediately".

Many of the comments relating to the drug interaction warning under § 330.1 (i) (formerly § 130.302(i)) stated that the pharmacist is a qualified health professional who is available, able, and educated to give advice to consumers concerning OTC products and drug interactions.

The Commissioner agrees that the pharmacist is a qualified health professional and does have knowledge about drug interactions and OTC medications.

There was also comment that, because of his knowledge and availability, the pharmacist should be included as a source of information in the drug interaction warning statement in § 330.1(i).

The Commissioner believes that the consumer should have available every source of reliable, helpful drug information. The proposal and final order stated that the patient's physician should be consulted on possible drug interactions because only he would be certain to know the identity of any prescription drugs being taken concurrently by the patient. It has been brought to the Commissioner's attention that other health professionals, such as physicians' assistants, nurses, nurse practitioners, dentists, and pharmacists, also may have this information and may be more readily available for consultation.

After a great deal of discussion and review, the Commissioner has concluded that the proper way to handle possible drug interactions is to require that the labeling include a separate section headed "Drug Interaction Precautions," stating the specific or general interaction problem involved with that particular OTC drug. Thus, in the final monograph on OTC antacid drugs published elsewhere in this issue of the FEDERAL REGISTER, a drug interaction precaution has been included for all aluminum-containing OTC antacid drug products stating that they should not be used concurrently with tetracycline. The same format will be used for other specific drug interactions found to exist in other monographs. Where known drug interactions exist but are not limited to a specific drug, the precaution statement shall be phrased in terms of general drug categories, such as has been required for charcoal which has been determined to be in Category III under the final order on OTC antacid drug products.

The Commissioner believes that this approach is more consistent with the concept of OTC drug labeling and with providing the most complete and useful information to consumers in concise terms. It directly advises the consumer that the drugs described are not to be used concurrently because of a possible drug interaction.

The purpose of OTC medication is to permit consumers to engage in self-medication without medical or other professional supervision, or in any event with the least amount of supervision feasible. Directing that consumers consult health professionals of any type would seem appropriate only if it is concluded that this is the only possible method of assuring the safe and effective use of the drug. Accordingly, although the Commissioner recognizes the availability of useful drug information through all health professionals, he concludes that it is unnecessary and inappropriate that they be designated on the label in any manner with respect to this particular matter in view of the availability of fully informative labeling which obviates such reference.

The Commissioner recognizes that all health professionals will continue to be a source of sound information on drugs, and encourages recent trends toward training of such persons in pharmacology and toxicology. The Commissioner also recognizes that, on occasion, a physician will wish to direct a patient to continue to use an OTC drug concurrently with a prescription drug contrary to a drug interaction precaution, where they are administered in a way that precludes interaction or other circumstances necessitate such action. In addition, consumers will be fully informed and protected by these labeling precautions.

The Commissioner has considered whether a standard format for a drug interaction precaution should be adopted. In view of the fact that no standard format for label warnings or other label statements has been prescribed in the section on general conditions, the Commissioner has concluded that there is no need to establish such a standard format in this instance. The format utilized in the final order for antacid drug products published elsewhere in this issue of the FEDERAL REGISTER will be utilized in future monographs except where good reason exists to vary from it. Accordingly, the Commissioner is proposing to revoke the warning as it presently exists in § 330.1(i) (formerly § 130.302(i)) of the regulations.

There were some comments by pharmacy organizations that a so-called "third class of drugs," under the control of pharmacists should be created by the Food and Drug Administration. The term "third class of drugs" has a slightly different meaning to different organizations. Some organizations would have the product dispensed only in a phar-

macy, others would have the product dispensed only by a pharmacist, and still others would require that the pharmacist keep a drug dispensing record similar to prescription drug records. The particular mechanics of a third class of drugs are not a significant issue as related to the Commissioner's appraisal of this proposal. Some comments specified that all OTC drugs with a drug interaction warning should be in this third class of drugs, and contended that the two issues are inseparable.

The Commissioner has spent a great deal of time reviewing the comments and discussing this issue with various groups, both in and out of the profession of pharmacy. The Federal Food, Drug, and Cosmetic Act requires that OTC drugs be safe and effective for lay use. Although the act permits imposition of whatever limitations or restrictions are necessary to assure the safe use of any drug, including restrictions on the channels of distribution, no controlled studies or other adequate research data have been supplied to support the position that any class of OTC drugs must be dispensed only by pharmacists in order to assure their safe use. It would be inappropriate to restrict the sale of OTC drugs to pharmacies based on anything less than proof that a significant safety issue was involved.

There were a number of comments stating that creating a third class of drugs would create an economic monopoly and an anticompetitive situation. The Department of Justice opposed any such restriction on antitrust grounds.

The Commissioner believes that these concerns are valid. Restricting the sale of some or all OTC drugs only to pharmacies would decrease the number of outlets where the consumer could purchase OTC products, limit competition, and raise some OTC drug prices, with no attendant public benefit. There is at this time no public health concern that would justify the creation of a third class of drugs to be dispensed only by a pharmacist or in a pharmacy. The "third class of drug" issue at this time is solely an economic issue. The Commissioner therefore categorically rejects the establishment of a third class of drugs at this time.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042, as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371)), the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended; (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that 21 CFR Part 330 be amended by revoking § 330.1(i) and by revising § 330.1(g) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(g) The labeling contains the general warning: "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The Food and Drug Administration will grant an exemption from this general warning where appropriate upon petition.

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(i) [Revoked]

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Interested persons are invited to submit their comments in writing (preferably in quintuplicate) regarding this proposal on or before August 5, 1974. Comments should be filed with the Hearing Clerk, Food and Drug Administration, Rm. 6–86, 5600 Fishers Lane, Rockville, MD 20852, and may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: May 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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