rector, employee, or agent of, or under the control, direction or influence of Beatrice or any of Beatrice's subsidiaries or affiliated corporations or who owns or controls more than one (1) percent of the outstanding shares of the capital stock of Beatrice.

III. It is further ordered, That, pending divestiture, respondent Beatrice shall not make or permit any deterioration in the value of any of the plants, machinery, parts, equipment, or other property or assets of the corporations to be divested which may impair their present capacity or market value unless such capacity or value be restored prior to divestiture.

IV. It is further ordered, That respondent Beatrice shall cease and desist for ten (10) years from the date this Order becomes final from acquiring directly or indirectly, through subsidiaries or otherwise, without prior approval of the Federal Trade Commission, any part of the assets, stock, share capital, or other actual or potential equity interest or right of participation in the earnings of any domestic concern, corporate or non-corporate, which is engaged in the manufacture of manually powered paint applicators or engaged in the manufacture or sale of raw materials to companies engaging in the manufacture of manually powered paint applicators, or from entering into any arrangements or understandings with such a concern through which respondent Beatrice becomes possessed of that concern's market share.

For the purpose of this Order, manually powered paint applicators are defined as: paint and varnish brushes; paint rollers, including pans, covers, handles, and other accessories sold separately, or as part of a paint roller kit; and miscellaneous paint applicators other than spray equipment and aerosol cans.

V. *It is further ordered*, That respondent Beatrice shall within sixty (60) days after date of service of this Order, and every sixty (60) days thereafter until respondent Beatrice has fully complied with the provisions of this Order, submit in writing to the Federal Trade Commission a verified report setting forth in detail the manner and form in which respondent Beatrice intends to comply or has complied with this Order. All compliance reports shall include, among other things that are from time to time required, a summary of contracts or negotiations with anyone for the specified stock, assets and plant, the identity of all such persons, and copies of all written communications to and from such persons.

VI. *It is further ordered*, That respondent Beatrice notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any change in the corporation which may affect compliance obligations arising out of the Order.

The Modified Order to Cease and Desist was issued by the Commission December 28, 1976.

JOHN F. DUGAN,
Acting Secretary.

[Docket No. 8864]

MODIFIED ORDER TO CEASE AND DESIST

In the Matter of BEATRICE FOODS CO., a corporation.

Respondent, having filed in the United States Court of Appeals for the Seventh Circuit on August 20, 1975, a petition to review an order to cease and desist issued herein on July 1, 1975; and the Court having rendered its decision and judgment on August 18, 1976, affirming and enforcing the Commission's order with a modification of Paragraph IV; and the time in which to file a petition for certiorari having expired without either party having filed such a petition;

Now, therefore, *It is hereby ordered*, That the aforesaid order to cease and desist be, and it hereby is, modified in accordance with the decision and judgment of the Court to read as follows:

ORDER

I.

It is ordered, That, subject to the prior approval of the Federal Trade Commission, respondent Beatrice, through its officers, directors, agents, representatives, employees, subsidiaries, affiliates, successors and assigns, shall as soon as possible and in any event within one (1) year from the date this Order becomes final, divest absolutely and in good faith all assets, rights, property and privileges, tangible and intangible, including all plants, equipment, machinery, raw material reserves, inventory, customer lists, trade names, trademarks, good will and other property of whatever description acquired by Beatrice as a result of its acquisition of Essex Graham Company (hereinafter referred to as Essex), including all additions and improvements thereto, which are necessary to restore Essex as a separate independent and viable going concern in the lines of commerce in which it was engaged prior to said acquisition.

II.

It is further ordered, That, pursuant to the requirement of Paragraph I above, none of the stock, assets, rights or privileges, tangible or intangible, acquired or added by Beatrice shall be divested directly or indirectly to anyone who is, at the time of the divestiture, an officer, director, employee, or agent of, or under the control, direction or influence of Beatrice or any of Beatrice's subsidiaries or affiliated corporations or who owns or controls more than one (1) percent of the outstanding shares of the capital stock of Beatrice.

III.

It is further ordered, That, pending divestiture, respondent Beatrice shall not make or permit any deterioration in the value of any of the plants, machinery, parts, equipment, or other property or assets of the corporations to be divested which may impair their present capacity or market value unless such capacity or value be restored prior to divestiture.

IV.

It is further ordered, That respondent Beatrice shall cease and desist for ten (10) years from the date this Order becomes final from acquiring directly or indirectly, through subsidiaries or otherwise, without prior approval of the Federal Trade Commission, any part of the assets, stock, share capital, or other actual or potential equity interest or right of participation in the earnings of any domestic concern, corporate or non-corporate, which is engaged in the manufacture of manually powered paint applicators or engaged in the manufacture or sale of raw materials to companies engaging in the manufacture of manually powered paint applicators, or from entering into any arrangements or understandings with such a concern through which respondent Beatrice becomes possessed of that concern's market share.

For the purpose of this Order, manually powered paint applicators are defined as: paint and varnish brushes; paint rollers, including pans, covers, handles, and other accessories sold separately, or as part of a paint roller kit; and miscellaneous paint applicators other than spray equipment and aerosol cans.

V.

It is further ordered, That respondent Beatrice shall within sixty (60) days after date of service of this Order, and every sixty (60) days thereafter until respondent Beatrice has fully complied with the provisions of this Order, submit in writing to the Federal Trade Commission a verified report setting forth in detail the manner and form in which respondent Beatrice intends to comply or has complied with this Order. All compliance reports shall include, among other things that are from time to time required, a summary of contracts or negotiations with anyone for the specified stock, assets and plant, the identity of all such persons, and copies of all written communications to and from such persons.

VI.

It is further ordered, That respondent Beatrice notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any change in the corporation which may affect compliance obligations arising out of the Order.

Issued: December 28, 1976.

By the Commission.

JOHN D. MACOLL,
Acting Secretary.

[FR Doc.77-3501 Filed 2-3-77; 8:45 am]

[Docket 8990]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Spiegel, Inc.

Codification under 16 CFR 13 appears at 40 FR 44317.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45.)

In the Matter of Spiegel, Inc., a corporation.

Order modifying an earlier order dated Aug. 18, 1975, 40 FR 44317, 86 F.T.C. 425, by limiting the reporting requirements of Paragraphs II and V, as mandated by the Court of Appeals for the Seventh Circuit in its August 9, 1976, decision and judgment, 540 F. 2d 303 (1976), to only those suits instituted in a county other than that where the defendant resided at the commencement of the action, or where he signed the contract sued on.

The Modified Order to Cease and Desist is as follows:

ORDER

I.

For purposes of this Order, the term "respondent" means "Spiegel, Inc., a

corporation, and its successors, assigns, officers, agents, representatives and employees, acting directly or through any corporation, subsidiary, division, or other device, including any collection agency."

II.

It is ordered, That respondent, in connection with the collection of retail credit accounts in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from instituting suits except in the county where the defendant resides at the commencement of the action, or in the county where the defendant signed the contract sued upon. This provision shall not be construed to prohibit the institution of suit by respondent against Illinois residents in an Illinois county courthouse which is a reasonable distance from their place of residence. This provision shall not preempt any rule of law which further limits choice of forum or which requires, in actions involving real property or fixtures attached to real property, that suit be instituted in a particular county.

III.

It is further ordered, That, where respondent learns subsequent to institution of a suit that the preceding Paragraph (II) has not been complied with, it shall forthwith terminate the suit and vacate any default judgment entered thereunder. In lieu of such termination, respondent may effect a change of forum to a county permitted by the preceding paragraph, *Provided*, That respondent gives defendant notice of such action and opportunity to defend equivalent to that which defendant would receive if a new suit were being instituted. In all cases respondent shall provide defendants with a clear explanation of the action taken and of the defendant's right to appear, answer and defend in the new forum.

IV.

It is further ordered, That where respondent terminates a suit or vacates a judgment pursuant to the preceding Paragraph (III) it shall give notice of such termination or vacation to each "consumer reporting agency," as such term is defined in the Fair Credit Reporting Act (51 U.S.C. Section 603), which it has been informed or has reason to know has recorded the suit or judgment in its files. Additionally, respondent shall furnish such notice to any other person or organization upon request of the defendant.

V.

It is further ordered, That respondent prepare and maintain a summary of suits involving the collection of retail credit accounts by respondent which were instituted in a county other than where the defendant resides, or where the defendant signed the contract sued upon. This summary shall contain each defendant's name, address, and county of residence; county where the contract was signed by the defendant; county where served; date served; date filed; docket number; name and location of court in which filed; name of plaintiff (if a collection agency suing in its own name); amount claimed; disposition (including garnishment or execution, if any); and explanation of the reason for choice of forum. This summary shall cover all such suits instituted, pending, terminated, or acted upon subsequent to judgment during the two years immediately following the effective date of this order. A copy of this summary shall be submitted to the Federal Trade Commission on a quarterly basis.

VI.

It is further ordered, That Spiegel, Inc., shall forthwith deliver a copy of this order to each of its subsidiaries and operating divisions, to each collection agency currently collecting any of Spiegel's retail credit accounts, and to any other collection agency prior to referral to it of any of Spiegel's retail credit accounts. Spiegel, Inc., shall obtain and preserve signed and dated statements from each collection agency, acknowledging receipt of the order and willingness to comply with it.

It is further ordered, That respondent shall notify the Commission at least thirty days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondent shall, within sixty days and at the end of six months after the effective date of the order served upon it, file with the Commission a report, in writing, signed by respondent, setting forth in detail the manner and form of its compliance with the order to cease and desist.

The Modified Order to Cease and Desist was issued by the Commission December 27, 1976.

JOHN F. DUGAN,
Acting Secretary.

[FR Doc.77-3502 Filed 2-3-77;8:45 am]

[Docket C-2858]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

California and Hawaiian Sugar Company, et al.

Subpart—Advertising falsely or misleadingly: § 13.10 Advertising falsely or misleadingly; 13.10-5 Knowingly by advertising agent; § 13.20 Comparative data or merits; 13.20-20 Competitors' products; § 13.160 Promotional sales plans; § 13.175 Quality of product or service; § 13.205 Scientific or other relevant facts. Subpart—Disparaging competitors and their products—Competitors' products: § 13.1015 Quality; § 13.1030 Source of origin. Subpart—Misrepresenting oneself and goods—Goods: § 13.1575 Comparative data or merits; § 13.1585 Competitive inferiority; § 13.1715 Quality; § 13.1740 Scientific or other relevant facts.—Promotional sales plans: § 13.1830 Promotional sales plans. Subpart—Offering unfair, improper and deceptive inducements to purchase or deal: § 13.2063 Scientific or other relevant facts.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45.)

In the Matter of California and Hawaiian Sugar Company, a corporation, and Foote, Cone & Belding/Honig, Inc., a corporation.

Consent order requiring a San Francisco, Calif., seller of granulated sugar, and its advertising agency, Foote, Cone and Belding/Honig, Inc., among other things to cease misrepresenting or making unsubstantiated claims regarding the superiority of their products over that of competing brands.

The order to cease and desist, including further order requiring report of compliance therewith, is as follows: [1]

ORDER

It is ordered, That respondents California and Hawaiian Sugar Company, a corporation, and Foote, Cone & Belding/Honig, Inc., a corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of granulated sugar packaged for retail consumption, forthwith cease and desist from:

1. Disseminating or causing the dissemination of any advertisement by means of the United States mails or in or having an effect upon commerce by any means, as "commerce" is defined in the Federal Trade Commission Act, which represents, directly or by implication:

(A) (i) That there are differences in granulated sugars, or that C&H granulated sugar derived from Hawaiian sugar cane is superior to or different from sugar derived from sugar beets or sugar cane from places other than Hawaii, unless (a) such represented difference or superiority relates to a consumer use of such sugar which is specified in the advertisement, (b) the difference or superiority is substantiated by competent and reliable evidence prior to making the representation, and (c) such substantiation includes competent and reliable evidence that the difference or superiority is discernible to or of benefit to the class of consumers to whom the representation is directed.

(ii) *Provided, however*, That it shall not be a violation of this Order to use the phrase "pure cane sugar from Hawaii" as a means of identifying the geographic origin and type of granulated sugar marketed under the C&H brand name in any context wherein the quality of the sugar marketed under the C&H brand is not expressly or implicitly com-

[1] Copies of the Complaint and decision and Order filed with the original document.

pared with the quality of any other sugar. Where an advertisement contains the phrase "pure cane sugar from Hawaii" and a depiction of C&H sugar, without any representation referring to any competitor's sugar product, or any representation that C&H sugar possesses a depicted characteristic or quality to a degree different from competitive brands of sugar, the advertisement will not be deemed to contain an implied comparison.

(iii) *It is further provided*, That if an advertisement makes a positive or absolute and truthful representation concerning C&H sugar without any representation concerning any competitor's sugar product, or without any representation that C&H sugar possesses a depicted characteristic or quality to a degree different from competitors' brands of sugar, the advertisement will not be deemed to contain an implied comparison under this order.

(B) That the label, advertising or packaging of any brand of granulated sugar other than C&H does not disclose the source or origin of its sugar, unless the advertisement specifies a consumer use of sugar with respect to which C&H sugar is different from such other sugar and such difference is substantiated by competent and reliable evidence prior to making the representation.

2. Disseminating, or causing the dissemination of, any advertisement by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of any such product, in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, which contains any of the representations prohibited in Paragraph 1 above.

Provided, however, That it shall not be considered a violation of this order for Foote, Cone & Belding/Honig, Inc. to make what would otherwise be a false or misleading claim or representation concerning the qualities of C&H sugars or competitive sugars if that respondent shows that it neither had any knowledge of the falsity of or misleading character of such representation nor had any reason to know, nor upon reasonable inquiry could have known its false, deceptive or misleading nature.

It is further ordered, That the respondent corporations shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered, That respondents notify that the Commission at least 30 days prior to any proposed change in the corporate respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

The Decision and Order was issued by the Commission January 6, 1977.

JOHN F. DUGAN,
Acting Secretary.

[FR Doc.77-3493 Filed 2-3-77;8:45 am]

Title 21—Foods and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 75N-0375]

INFORMAL HEARING BEFORE REPORT OF CRIMINAL VIOLATION

The Food and Drug Administration (FDA) is issuing final regulations that set forth procedures for an informal hearing before report of criminal violation, effective March 7, 1977.

The Commissioner of Food and Drugs issued a proposal in the FEDERAL REGISTER of April 7, 1976 (41 FR 14769) to adopt rules on the internal practices and procedures of the agency governing informal hearings conducted pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335). The provisions of § 1.6 *Presentation of views under section 305 of the act* (21 CFR 1.6), which were brief and general, are expanded under new § 2.705 (21 CFR 2.705). The regulations being adopted deal with the conduct of an informal hearing under § 2.706 (21 CFR 2.706) and the disclosure of records relating to such hearings under § 2.707 (21 CFR 2.707).

The Commissioner further proposed to add to Part 2 (21 CFR Part 2), new Subpart N, Enforcement Policy, Practices, and Procedures, to accomplish the purpose set forth in § 2.700 *Scope and purpose* (21 CFR 2.700). The proposal included new § 2.703 *Definitions* (21 CFR 2.703), containing definitions applicable to Subpart N generally and to section 305 hearings specifically. As regulations governing other facets of agency regulatory enforcement practices and procedures are promulgated, necessary additional definitions will be included in § 2.703.

Eight letters were received in response to the proposal. The comments in the letters and the Commissioner's conclusions about them are as follows:

1. One comment took exception to a reference in the preamble to the statutory authority of the agency over product recalls.

A complete discussion of recall authority and procedures was published in the FEDERAL REGISTER of June 30, 1976 (41 FR 26924), and the reader is referred to that document. The Commissioner also notes that the Radiation Control for Health and Safety Act (Pub. L. 90-602) and the Medical Device Amendments of 1976 (Pub. L. 94-295, enacted May 28, 1976) contain specific recall authority. In any event, since the comments dealt with the statement in the preamble, no change in the regulation with respect to section 305 hearings is necessary.

2. One comment argued that individual respondents at section 305 hearings should be given "Miranda" warnings, particularly advice that a respondent has a right to remain silent and that anything he says may be used against him.

As the Commissioner noted in the preamble to the proposal, "Miranda" type warnings are inapplicable to situations, like section 305 hearings, where there is no custodial interrogation. The fact that custodial interrogation is the essential touchstone of the rule in "Miranda" has been reaffirmed by the Supreme Court recently in "Beckwith v. United States," 96 S. CT. 1612 (1976), notwithstanding the fact that the inquiry challenged there had focused upon a person who appeared to have violated the law. This decision is consistent with earlier rulings of the Supreme Court reaffirming the limited applicability of "Miranda" to "custodial" interrogations. "Mathis v. United States," 391 U.S. 1 (1968) and "Orozco v. United States," 394 U.S. 324 (1969). Moreover, the Notice of Hearing, accompanying Information Sheet, and the regulations themselves make clear that appearance is voluntary because a person need not appear or answer in any manner to a Notice of Hearing, that a person who chooses to appear may do so with legal counsel, that the hearing concerns potential criminal prosecution, and that information presented by a respondent at a hearing may be introduced at a subsequent trial. (See §§ 2.705(e) and 2.706 (b)(4) below.) The voluntariness of statements made at section 305 hearings and the inapplicability of the "Miranda" type warnings have been specifically recognized in cases arising under the Federal Food, Drug, and Cosmetic Act. "United States v. Andreadis," 234 F. Supp. 341 (E.D. N.Y., 1964) and "United States v. Newton," No. 4-66 Cr. 45 (D. Minn., 1966).

3. One comment sought assurance that persons who receive a supplemental Notice of Hearing will be entitled to the same procedures and safeguards as afforded those who receive an original Notice of Hearing.

The Commissioner advises that anyone receiving a Notice of Hearing, whether it be original or supplemental, will be subject to the same procedures. The regulation does not provide different procedures or "safeguards" for original and supplemental notices.

4. Four comments were received concerning whether section 305 hearings should always be provided to those persons being considered for prosecution. One comment suggested that the hearings are unnecessary and should not be provided under any circumstances. Two comments suggested that all persons being considered for prosecution should be granted a hearing without exception and objected to that portion of § 2.705(a) dispensing with an opportunity for a hearing "in compelling circumstances." The fourth comment argued that the proposed rules may create a right which will be binding but which was never intended by Congress and does not exist in the statute.

As noted in the preamble of the proposal, the United States Supreme Court has authoritatively determined that a hearing by FDA is not a prerequisite to prosecution under the act. Nevertheless, the agency has decided that it will normally provide an opportunity for an administrative hearing before issuing a prosecution recommendation to a United States attorney. There may be circumstances, however, in which a section 305 procedure would be unwarranted, such as where a person had already had an opportunity to explain his or her role with respect to a violation in the context of a prior injunction proceeding. There are other situations that may justify making an exception to the general rule. Accordingly, FDA will give notice and opportunity for an informal hearing "except in compelling circumstances." The decision to establish a general rule providing for a notice and opportunity for a hearing does not preclude imposition of reasonable terms, limits, or conditions upon such procedures.

Because the regulation is intended to apply only to FDA, it has no effect upon the independent decisions and procedures of the Department of Justice in instituting criminal proceedings under the Federal Food, Drug, and Cosmetic Act. As Congressman Lea, Chairman of the House Interstate and Foreign Commerce Subcommittee, made clear in the legislative debates:

> Mr. LEA. I call attention, however, to the fact that the mere circumstance that the [Commissioner] does not report the offense does not excuse the accused from prosecution. The Attorney General may proceed in case he desires to do so. * * * The law speaks for itself, and there are no strings on the Department of Justice or on the grand jury. They can proceed whenever they like. 83 Cong. Rec. 10249.

Sections 2.705(a), 2.706(h) and 2.706(i) are being modified and new paragraph (j) is being added to § 2.706 to specify FDA as the government agency to which these informal hearing regulations apply and to delineate the distinction between the duties of the agency and absence of restraints upon the Department of Justice.

5. A comment suggested that reference to the "Department of Justice" should replace the phrase "United States attorney" in the regulations.

The Commissioner disagrees. The statute refers to reporting proposed prosecutions to "any United States attorney." Although a copy of the FDA written recommendations for prosecution is also routinely sent to the appropriate section of the Department of Justice, this is not reason to alter the statutory designation of the United States attorney, to whom the agency's recommendation is made.

6. A comment noted that the definition of "person" in proposed § 2.703(d) is not identical to that which appears in section 201(e) of the act (21 U.S.C. 321 (e)) in that the regulaion added the phrase "or other legal entity."

The Commissioner concludes that the definition of "person" shall be removed from the regulation because it already appears in the act.

7. One comment suggested that the definition of "responsible individual" should be deleted from proposed § 2.705 (b) because it will appear elsewhere in the regulations.

The Commissioner has decided that the term should be part of the definitions section; it is designated as § 2.703 (d) in the final regulation.

8. Two comments requested that the regulation be revised in § 2.705(c)(1) to require that the Charge Sheet include details of the conduct forming the basis of an alleged violation, rather than a summary of the violations.

The Commissioner agrees that respondents must be sufficiently informed to prepare a response. Current procedure provides for itemization of the specific products and shipments forming the basis of the contemplated action in the Notice of Hearing. Section 2.705(c) is revised in the final order to refer to the substance of a Notice of Hearing. It has been the experience of FDA that respondents have no difficulty understanding the charges or preparing relevant responses. Only occasionally have hearing officers been requested to give additional clarification. The format and the content of the hearing documents will continue to provide adequate information and therefore are not being changed at this time.

9. One comment objected to the nonspecificity of the requirement in proposed § 2.705(g) that requests for separate hearings be made "seasonably" and recommended that the term be clarified.

The Commissioner agrees with this comment. The final regulation provides that requests for a separate hearing must be received at the designated hearing office at least 3 working days before the scheduled hearing date. Because proposed § 2.705(d) was subject to the same criticism, the Commissioner is combining proposed § 2.705 (d) and (g) in the final regulation to provide in new § 2.705 (d) specific time limits governing all requests for changes in the date, time, or place of hearing.

10. Two comments stated that the regulation was unclear in proposed § 2.706 (b) as to who might appear at the hearings to represent a person named in the Notice of Hearing. One comment further noted that a designated representative might appear pursuant to § 2.705(f) as proposed but fail to present written authorization, in which case, presumably, the hearing could not proceed.

The Commissioner concludes that because a section 305 hearing is not open to the public, all persons attending, other than FDA officials, must appear at the request of and on behalf of the respondent; § 2.706(b)(2) is modified to clarify this limitation. If someone appears at a hearing claiming to be the designated representative of a person named in a Notice of Hearing, but without written authorization, the hearing officer shall attempt to verify the claim by telephone or other means before beginning the hearing. Such verification is acceptable in those circumstances and § 2.705(f) is amended in the final regulation to provide for this procedure. If however, proper verification cannot be obtained for a respondent, the hearing with respect to that respondent will not be held at that time.

11. A related comment suggested that the regulations provide for additional FDA personnel to be present at section 305 hearings to assist the hearing officer or for training or other purposes.

The Commissioner concurs in this suggestion and § 2.706(a) is amended to provide for the presence of additional FDA personnel.

12. One comment suggested that the investigator who observed the alleged violations be present at section 305 hearings to assure that the person charged has the opportunity to bring out all pertinent facts.

Section 305 hearings were not intended to be adversary proceedings, but rather were designed to provide an opportunity for a respondent to present his views. For this reason, § 2.706(b)(3) as proposed provided that the "Food and Drug Administration is under no obligation to present evidence or witnesses." Moreover, hearing officers are sufficiently aware of the facts of each case so that they may clarify any charges that may be questioned. Therefore, this suggestion is rejected.

13. One comment recommended that §§ 2.706 (c) and (d) be modified to provide that a summary of the hearing be dictated whether or not a verbatim transcript is prepared.

While recognizing that hearing transcripts may be delayed, the Commissioner does not believe that two separate documents are necessary or desirable. It is anticipated that hearing officers will retain their notes until transcripts are received and they may prepare internal memoranda to promptly advise their supervisors. Any time taken awaiting a hearing transcript will not adversely affect a respondent's ability to submit written supplemental comments pursuant to § 2.706(g) of the regulations.

14. Two comments suggested that respondents (1) be permitted to remain during the dictation of the summary in order to comment or suggest corrections or (2) have 10 calendar days to review the transcript or summary of a hearing to provide written comments.

The Commissioner concurs. Sections 2.706 (d) and (g) of the final regulation are revised to provide both an opportunity to await dictation of the summary and make comment at that time, as well as 10 calendar days for written supplementation upon receipt of the summary or transcript.

15. One comment suggested that the standard for reopening hearings be modified to permit a hearing to be reopened when a respondent demonstrates only that new information has come to light that could affect the FDA decision to prosecute but not also, as proposed, that such information was not previously

readily available. The comment also suggested that a respondent be allowed to supplement his presentation with written or documentary material at any time prior to a recommendation for prosecution.

In response to this suggestion, § 2.706 (g) has been revised to provide assurance that supplemental materials, submitted by a respondent within 10 calendar days after the date of a written response to a Notice of Hearing or 10 calendar days after the date that respondent receives the transcript or the summary of hearing, shall be considered before the final agency decision. The final order states that any supplemental materials received after the 10-day response period will be considered and added to the record of hearing only if the final decison has not already been made.

The Commissioner believes that a demanding standard should be maintained for the reopening of hearings since there are procedures to submit supplemental materials in documentary form. For this reason, § 2.706(e) has been modified to require that requests for a reopened hearing specify the nature of the new information, the reason why it was not previously available to the respondent, and the reason it should not be submitted in documentary form. The final regulation provides that a hearing will be reopened only if the information to be submitted was not reasonably available to the respondent at the time of the initial hearing.

16. Three comments recommended that §§ 2.706(h) and (i) be amended to provide that decisions to prosecute persons afforded a 305 hearing be made within a specified time and that all persons charged should be notified of the decision.

The Commissioner rejects the suggestion that FDA be bound to a prescribed review time. Responses to section 305 notices may be brief or extensive, including laboratory analyses. On occasion, legal memoranda and other documentary evidence is submitted. Of course, a person named in a notice need not appear at all. In view of these variables, and the benefit to a respondent of the full consideration of the case at the various levels of review beyond the FDA district office, it would be not only artificial but detrimental to impose a time limitation. The timeliness of prosecution for violations of the act will be measured by statute of limitations.

With respect to notification of the agency's decision not to prosecute, the Commissioner has concluded that each named individual will be notified immediately when consideration of criminal prosecution is closed with respect to all such persons, as set forth under § 2.706 (h). Where prosecution of some named persons is recommended to a United States attorney, notification of those not recommended for prosecution will be made only if such notification will not prejudice the prosecution of the potential defendants, as set forth under § 2.706 (i). The Commissioner concludes that the risk of prejudice to a subsequently named defendant outweighs the delay in advising those who are no longer being considered by the agency for criminal prosecution.

17. One comment objected to that portion of § 2.707(c) that permits the name of a person considered for prosecution, but not prosecuted, to be disclosed under the Freedom of Information Act (5 U.S.C. 552) if the Commissioner concludes there is compelling public interest to do so. The comment asserted that in no situation would the public interest be served and that, if the names are to be released, it should only be with the consent of the named individual.

The Commissioner can envision situations in which the fact that a person was considered by the agency for prosecution but not found to be responsible is preferable to the implication that inculpatory evidence exists in agency files. Since the regulation provides that release is measured by a compelling public interest, written consent of the individuals involved should not be required. Section 2.707(c) is consistent with its predecessor, § 1.6(c)(4) (21 CFR 1.6(c)(4)), and with the agency's regulation on disclosure of public information in § 4.64(d)(4) (21 CFR 4.64(d)(4)). Accordingly, the comment is rejected.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)); *It is ordered*, That Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

§ 1.6 [Revoked]

1. In Part 1, by revoking § 1.6 *Presentation of views under section 305 of the act.*

PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

2. In Part 2 by adding new Subpart N, consisting of the following sections:

Subpart N—Enforcement Policy, Practices, and Procedures

Sec.
2.700 Scope and purpose.
2.703 Definitions.
2.705 Informal hearing before report of criminal violation.
2.706 Conduct of informal hearing before report of criminal violation.
2.707 Records related to hearings conducted before report of criminal violation.

AUTHORITY: Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)).

Subpart N—Enforcement Policy, Practices, and Procedures

§ 2.700 Scope and purpose.

Subpart N of Part 2 governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This subpart is promulgated to clarify and explain the regulatory enforcement practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

§ 2.703 Definitions.

(a) "Agency" means the Food and Drug Administration.

(b) "Notice of Hearing" means the document (Form FD-466), also referred to as a "citation" or "cite," that provides notice to a person against whom criminal prosecution is contemplated of the opportunity to present his views to the agency regarding an alleged violation.

(c) "Other laws administered by the Food and Drug Administration" includes, but is not limited to, the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), the Federal Caustic Poison Act (15 U.S.C. 401–411), the Radiation Control for Health and Safety Act (42 U.S.C. 263b–263n), and provisions of the Public Health Service Act relating to biologics (section 351 (42 U.S.C. 262)), and interstate quarantine, including milk and food service and shellfish sanitation, (section 361 (42 U.S.C. 264)).

(d) "Responsible individual" includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) "Respondent" means a person named in a Notice of Hearing, who either in person, by designated representative, or in writing presents his views concerning an alleged violation.

§ 2.705 Informal hearing before report of criminal violation.

(a) A person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is being contemplated by the Food and Drug Administration shall, except in compelling circumstances, be given appropriate notice and an opportunity for an informal hearing before the agency to present information and views to show cause why institution of criminal prosecution should not be recommended to a United States attorney.

(b) An opportunity for such a hearing shall be afforded all persons who, in the judgment of the Food and Drug Administration, appear to have had a responsible share in the furtherance of a transaction that violates the law.

(c) Opportunity for hearing shall be provided by a Notice of Hearing (Form FD-466) sent to each person who appears to share responsibility for a violation. A Notice of Hearing shall identify the products and/or shipments alleged to be in violation, and shall be sent by registered or certified mail, telegram, telex, personal delivery, or any other

appropriate mode of written communication. The Notice of Hearing shall specify the time and place of the hearing and shall be accompanied by:

(1) A Charge Sheet (Form FD-1854) summarizing the apparent violations of the act and of other laws administered by the agency that constitute the basis of the contemplated prosecution.

(2) An Information Sheet (Form FD-466a) describing the purpose and procedure of the hearing.

(3) A Legal Status Sheet (Form FD-454) which the respondent is requested to fill out and return with the response to the Notice of Hearing.

(d) If more than one person is named in a Notice of Hearing, a separate hearing for any named person shall be scheduled on request. Otherwise, the time and place specified for a hearing may be changed only upon a showing of reasonable grounds. Requests for any change shall be addressed to the office in the Food and Drug Administration that issued the Notice of Hearing and shall be received in that office at least 3 working days before the date set in the Notice of Hearing.

(e) A person who has received a Notice of Hearing is under no legal obligation to appear or answer in any manner. If a person chooses to respond, he may appear personally, with or without a representative, or he may designate a representative to appear for him. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled for the hearing, the Food and Drug Administration will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the evidence available.

(f) When a respondent chooses to appear solely by designated representative, such representative shall present to the hearing officer a signed statement of authorization. When a representative appears for more than one respondent, he shall submit independent documentation of his authority to act for each. If a representative appears without written authorization, the hearing with respect to that respondent may proceed only if the hearing officer first verifies by telephone, or other appropriate means, the authenticity of the representative.

§ 2.706 Conduct of informal hearing before report of criminal violation.

(a) The hearing shall be conducted by a Food and Drug Administration employee who has been designated as a hearing officer. Other Food and Drug Administration employees may be present, and the purpose of their attendance will be stated for the record.

(b) The hearing shall be conducted in the following fashion:

(1) The hearing shall commence at the time and place designated in the Notice of Hearing, or as otherwise agreed to by the participants.

(2) The hearing shall not be open to the public. The hearing officer will permit participation of other persons only if they appear with the respondent or his designated representative and at the request of and on behalf of the respondent, provided they identify themselves and their relationship to the respondent and state on the record that they are appearing for the respondent.

(3) The hearing shall be informal and shall be conducted in a manner that facilitates the presentation of information and views by the respondent. Rules of evidence shall not apply. At the outset, the hearing officer shall briefly review the basis on which criminal prosecution is contemplated. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(4) A respondent may present any information bearing on why he should not be prosecuted. Such information may consist of statements of persons appearing on his behalf, letters, documents, laboratory analyses, if applicable, or any other data or arguments relevant to the allegations set forth in the Charge Sheet. Such information, including statements by the respondent, may be introduced at at any subsequent trial.

(5) If the respondent holds a "guaranty or undertaking" (as described in section 303 of the act (21 U.S.C. 333(c))) that is applicable to any article on which the Notice of Hearing is based, such guaranty or undertaking, or verified copy thereof, may be presented by the respondent. Such document will be made a part of the record of the hearing.

(c) The respondent shall have the right to have the hearing transcribed at his expense, in which case a copy of such transcription shall be furnished to the Food and Drug Administration. Alternatively, the hearing officer may, at his discretion, order the hearing transcribed at the expense of the Food and Drug Administration, in which case a copy of such transcription shall be provided to each respondent.

(d) If the hearing is not transcribed, the hearing officer shall dictate a written summary of the hearing at its conclusion. The respondent shall be offered the opportunity to remain during the dictation to offer additional comments or corrections. A copy of the completed written summary shall be provided to each respondent whether or not he remains during dictation. Respondents may submit comments on the summary in accordance with paragraph (g) of this section.

(e) If a respondent obtains new information that was not reasonably available to him at the time of the hearing, a timely written request to reopen the hearing may be submitted to the office in the Food and Drug Administration where the hearing was held. Such a request shall specify the nature of the new information sought to be presented, the reason why it was not previously available to the respondent, and the reason it should not be submitted in documentary form. If the Commissioner concludes that presentation of the information may have a bearing on the decision to prosecute, he shall designate an employee of the Food and Drug Administration to conduct the reopened hearing. Any reopened hearing shall be governed by the procedures set forth in this subpart, and the written request and the summary or transcript of the reopened session shall become part of the record of the hearing.

(f) The record of the hearing shall consist of the following:

(1) The Notice of Hearing.

(2) The Charge Sheet.

(3) The Legal Status Sheet, if completed and returned by the respondent.

(4) All documentary information submitted by the respondent.

(5) The transcript or summary of the hearing and of any reopened session of such hearing.

(g) A respondent may supplement any response made on his behalf with additional written or documentary evidence and/or provide written comment on the summary of hearing or the transcript. To ensure that any submission will receive consideration before the agency decides whether or not to recommend prosecution, such submission shall be furnished to the office in the Food and Drug Administration where the hearing was held no later than 10 calendar days after either the date of a written response to a Notice of Hearing or the date the respondent receives the transcript or the summary of hearing. Any materials received after the 10-day supplemental response period has expired will be considered and added to the record of hearing if the final decision has not yet been made. Any such supplemental material shall be made a part of the record of the hearing.

(h) When consideration of criminal prosecution involving the same violations is closed by the agency with respect to all persons named in the Notice(s) of Hearing and no further criminal action is contemplated for the offenses charged, the agency will so notify each person in writing.

(i) When it is finally determined that a person named in a Notice of Hearing will not be included in the agency recommendation for prosecution, the agency will notify that person, if and when it concludes that notification will not prejudice the prosecution of any other person.

(j) When a United States attorney informs the agency that he will prosecute some but not all persons who had been provided an opportunity for a hearing and were subsequently named in an agency recommendation for prosecution, the Food and Drug Administration will notify those persons eliminated from further consideration after being advised by the United States attorney that such notification will not prejudice the prosecution of any other person. When a United States attorney informs the agency that no persons recommended by the agency will be prosecuted, the agency will so notify each person in writing.

§ 2.707 Records related to hearings conducted before report of criminal violation.

(a) Records relating to a section 305 hearing constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memoranda.

(1) Notwithstanding the rule established in § 4.21 of this chapter, no record relating to a section 305 hearing is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 4.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise his discretion to disclose records (pursuant to § 4.82 of this chapter) relating to a section 305 hearing before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed such records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in Subpart D of Part 4 of this chapter are applicable. No statements of persons obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based upon a particular section 305 hearing shall be deemed to be closed within the meaning of this section and § 2.706 when a final decision has been made not to recommend criminal prosecution to a United States attorney based upon charges set forth in the Notice of Hearing and considered at that hearing, or such recommendation has been finally refused by the United States attorney, or criminal prosecution has been instituted and the matter and all related appeals have been concluded, or the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but who was not recommended for prosecution or, if recommended for prosecution was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from section 305 hearing records before public disclosure only pursuant to § 4.32 of this chapter.

PART 4—PUBLIC INFORMATION

§ 4.21 [Amended]

3. Section 4.21 *Uniform access to records* is amended in paragraph (b) by changing the reference to "§ 1.6(c)(1)" to read "§ 2.707(a)(1)."

§ 4.64 [Amended]

4. Section 4.64 *Investigatory records compiled for law enforcement purposes* is amended in paragraph (c)(2) by changing the reference to "§ 1.6(c)" to read "§ 2.707."

§ 4.100 [Amended]

5. Section 4.100 *Applicability; cross-reference to other regulations* is amended in paragraph (c)(1) by changing the reference to "§ 1.6(c)" to read "§ 2.707."

Effective date. This regulation shall become effective March 7, 1977.

(Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 355, 371(a)).)

Dated: January 28, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-3339 Filed 2-3-77;8:45 am]

[Docket No. 77N-0008]

PART 8—COLOR ADDITIVES

Listing of FD&C Yellow No. 5 for Cosmetic Use Subject to Certification; Stay of Effectiveness

The Food and Drug Administration (FDA) is announcing a stay of the effectiveness of the order listing FD&C Yellow No. 5 for use in externally applied cosmetics.

In the FEDERAL REGISTER of January 21, 1974 (39 FR 2358), the Commissioner of Food and Drugs issued an order listing FD&C Yellow No. 5 for use in externally applied cosmetics other than hair straighteners, permanent wave preparations, and depilatories by adding new § 8.7255 (21 CFR 8.7255). The continued use of these three types of products has been permitted under the provisional listing of FD&C Yellow No. 5.

Timely objections to the order were received from a manufacturer of colors, a manufacturer of cosmetics, and a trade association. Two of the letters objected to the order's exclusion of the use of FD&C Yellow No. 5 in ingested cosmetics. Both letters claimed that such use should be included in the order and cited findings from teratological and multireproduction studies as supporting evidence for their safe use. It was also cited that the color was already listed for use in food and ingested drugs. Two of the letters objected to the exclusion of the use of the color in hair straighteners, permanent wave preparations, and depilatories. One letter objected to the omission of a final listing of lakes made from FD&C Yellow No. 5. One letter objected to the omission of the use of FD&C Yellow No. 5 in externally applied drugs. The filing of these objections automatically served to stay the effectiveness of the order because they involved its primary aspects.

A proposal was published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860) to postpone the closing dates for the provisional listing of certain color additives beyond December 31, 1976. One of the requirements that the proposal would impose is the submission of new data from chronic studies with certain color additives, including FD&C Yellow No. 5. The Commissioner, in evaluating the listing of FD&C Yellow No. 5 for external cosmetic use, concludes that such action is inappropriate pending receipt of the new data from chronic studies with FD&C Yellow No. 5.

Accordingly, the Commissioner is announcing in accordance with section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), that the effectiveness has been stayed for the order listing FD&C Yellow No. 5 for use in externally applied cosmetics.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 706(b), (c), and (d), 70 Stat. 919, 74 Stat. 399–403 (21 U.S.C. 371(e), 376(b), (c), and (d))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), notice is given that the effective date of March 22, 1974 for the order amending Part 8 by adding new Subpart G consisting of § 8.7255 is stayed by the filing of timely and valid objections.

Until further notice, FD&C Yellow No. 5 will continue to be provisionally listed for use in cosmetics, generally, and in externally applied drugs.

Dated: January 28, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-3337 Filed 2-3-77;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Exempt Chemical Preparations

The Administrator of the Drug Enforcement Administration has received applications pursuant to § 1308.23 of Title 21 of the Code of Federal Regulations requesting that several chemical preparations containing controlled substances be granted the exemptions provided for in § 1308.24 of Title 21 of the Code of Federal Regulations.

The Administrator hereby finds that each of the following chemical preparations and mixtures is intended for laboratory, industrial, education, or special research purposes, is not intended for general administration to a human being or other animal, and either (a) contains no narcotic controlled substances and is packaged in such a form or concentration that the package quantity does not present any significant potential for abuse, (b) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration, that the preparation or mixture does not present any potential for abuse, or (c) the formulation of such preparation or mixture incorporates methods of denaturing or other means so that the controlled substance cannot

in practice be removed, and therefore the preparation or mixture does not present any significant potential for abuse. The Administrator further finds that exemption of the following chemical preparations and mixtures is consistent with the public health and safety as well as the needs of researchers, chemical analysts, and suppliers of these products.

Therefore, pursuant to section 202(d) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 812(d)), and under the authority vested in the Attorney General by sections 301 and 501(b) of the Act (21 U.S.C. 821 and 871(b)) and delegated to the Administrator of the Drug Enforcement Administration by, and in accordance with, Regulations of the Department of Justice (Title 28 of the Code of Federal Regulations, Part 0), the Administrator of the Drug Enforcement Administration hereby orders that Part 1308 of Title 21 of the Code of Federal Regulations be amended as follows:

a. By amending § 1308.24(i) by adding the following chemical preparations:

§ 1308.24 Exempt chemical preparations.

* * * * *

(i) * * *

Manufacturer or supplier	Product name and supplier's catalog No.	Form of product	Date of application
Templi® Division, Big Three Industries, Inc.	TEMPILAR® STRIPED MYLAR	Plastic sheet: 6 by 12 in. 50 sheets per envelope.	Sept. 22, 1976
Materials & Technology Systems, Inc.	Methadone standard	Screwcap vial: 10 ml	Sept. 17, 1976
Do	Barbiturate standard	do	Do.
Do	Benzoyl ecgonine (cocaine) standard	do	Do.
J. T. Baker Chemical Co., Diagnostics Division.	TOXI-PAK® Immuno HI™ morphine-sensitized red blood cells, product No. 10701.	Bottle: 20 ml	Sept. 20, 1976
Do	TOXI-PAK® Immuno HI™ morphine standard, product No. 10703.	Bottle: 8 ml	Do.
Do	TOXI-PAK™ Immuno HI™ morphine kit, product No. 10700.	Kit: 200 determinations	Do.
Do	TOXI-PAK™ Immuno HI™ methadone standard product No. 10708.	Bottle: 8 ml	Do.
Do	TOXI-PAK™ Immuno HI™ methadone kit, product No. 10705.	Kit: 200 determinations	Do.
Bio-Reagents & Diagnostics, Inc.	Ortho toxicology control serum, product No. 9070.	Bottle: 10 ml	Sept. 15, 1976
Do	Ortho toxicology control urine proficiency, product No. 9075.	Bottle: 25 ml	Do.
Do	Ortho anticonvulsant control serum, product No. 9085.	Bottle: 10 ml	Do.
Becton, Dickinson & Co. Schwarz/Mann Division.	Human thyroid stimulating hormone radioimmunoassay kit (^{125}I), catalog No. 224219.	Kit: 100 determinations	Oct. 8, 1976
Do	Thyroid stimulating hormone (^{125}I), catalog No. 224316.	Glass vial: 10 cc	Do.
Do	Thyroid stimulating hormone antiserum, catalog No. 224413.	do	Do.
Do	Precipitating antiserum, catalog No. 224511	do	Do.
Do	Barbital buffer, catalog No. 224618	do	Do.
Do	Human thyroid stimulating hormone:		
	Standard A, catalog No. 225812	do	Do.
Do	Standard B, catalog No. 225928	do	Do.
Do	Standard C, catalog No. 225011	do	Do.
Do	Standard D, catalog No. 225118	do	Do.
Do	Standard E, catalog No. 225218	do	Do.
Flow Laboratories	Human "O" DGV (dextrose gelatin veronal buffer).	Glass vial: 100 ml	Oct. 14, 1976
Microbiological Associates, division of Whittaker Corp.	Veronal buffer (5×concentrated for LBCF text), product No. 17-744.	Glass bottle: 500 ml, 100 ml.	Oct. 18, 1976
Do	Veronal buffer (5×concentrated), product No. 12-624.	Glass bottle: 100 ml	Do.
Do	Dextrose-gelatin-veronal (DGV) solution, product No. 10-539.	Glass bottle: 500 ml, 100 ml.	Do.
Amersham/Searle	T-4 TIA(PEG) kit catalog code IM.92	Kit: 50 determinations	Nov. 10, 1976
Do	T-4 RIA(PEG) kit catalog code IM.921	Kit: 100 determinations	Do.
Do	Thyroxine (^{125}I)	Vial: 100 mg	Do.
Do	Antiserum	Vial: 100 mg	Do.
Union Carbide Corp. (clinical diagnostics).	Centria test-T_4 kit	Kit: 36 determinations	Nov. 15, 1976
Do	Thyroxine antiserum	Amber vial: 10 ml	Do.
Do	Thyroxine radiolabel	Amber vial: 5 ml	Do.
Do	T_4 eluant	Amber vial: 100 ml	Do.
Do	Nonspecific binding	Amber vial: 5 ml	Do.
Do	Separation columns	Securitainers: 10 plastic columns, ¾ in diameter and 4 in long each.	Do.
Micromedic Systems	T_4 RIA ^{125}I tracer solution	Vial: 30 ml	Dec. 14, 1976
Do	T_4 RIA buffer solution	High density polyethylene bottle: 8 oz.	Do.
Do	T_3 RIA buffer solution	do	Do.
Do	T_3 RIA ^{125}I tracer solution	Vial: 30 ml	Do.
Do	T_3 uptake buffer solution	High density polyethylene bottle: 8 oz.	Do.
Do	T_3 uptake ^{125}I tracer solution	Vial: 30 ml	Do.

Effective date. This order is effective February 4, 1977. Any person interested may file written comments on or objections to the order on or before March 25, 1977. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke or amend his original order as he determines appropriate.

Dated: January 26, 1977.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc.77-3387 Filed 2-3-77;8:45 am]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER A—INCOME TAX

[T.D. 7459]

PART 7—TEMPORARY INCOME TAX REGULATIONS UNDER THE TAX REFORM ACT OF 1976

Various Elections

Correction

In FR Doc. 77-703, appearing at page 1469 in the issue for Friday, January 7, 1977, in § 7.0(d), the sixth line which appears at the bottom of the second column on page 1470 should read "graphs (c)(1)(i), (c)(4) and (c)(5) * * *"

Title 29—Labor

CHAPTER IV—OFFICE OF LABOR-MANAGEMENT STANDARDS ENFORCEMENT, DEPARTMENT OF LABOR

SUBCHAPTER A—LABOR-MANAGEMENT REPORTS

PART 402—LABOR ORGANIZATION INFORMATION REPORTS

Subsequent Reports

On November 19, 1976, notice of a proposed amendment to 29 CFR 402.4 was published in the FEDERAL REGISTER (41 FR 51040). 29 CFR 402.4 concerns the filing of Form LM-1A, "Report of Current Status: Labor Organization Information Supplement," by labor organizations to update the information previously filed by the labor organizations on Form LM-1, "Labor Organization Information Report," or on a previously filed Form LM-1A and to update the constitution and bylaws or other documents filed with those reports. Form LM-1A and the documents prescribed by the instructions to the forms are currently required to be filed for each annual reporting period in which there have been changes in the labor organization's constitution and bylaws or in the practices or procedures for which separate statements were filed by the labor organization in response to question 18 on Form LM-1 or question 10 on Form LM-1A.

If a subordinate labor organization adopts or has adopted as its constitution and bylaws a uniform constitution and bylaws prescribed by its parent national or international labor organization, it is not required to file such a uniform constitution and bylaws with its initial information report on Form LM-1 or with any subsequent filing of Form LM-1A if the parent national or international labor organization files as many copies of the constitution and bylaws with the Director of the Office of Labor-Management Standards Enforcement (LMSE) as the Director may request. Since the primary purpose of Form LM-1A is to insure that up-to-date copies of a labor organization's constitution and bylaws and other governing rules are filed with LMSE, it has been determined that it is unnecessarily burdensome to require the filing of Form LM-1A by subordinate labor organizations for a reporting period in which the only changes in their governing rules were changes in