PART 375—[AMENDED]

3. The authority citation of Part 375 continues to read as follows:

Authority: Electric Consumers Protection Act of 1986, Pub. L. 99-495; Department of Energy Organization Act, 42 U.S.C. 7101-7532, E.O. 12,009, 3 CFR 1977 Comp., p. 142; Administrative Procedure Act, 5 U.S.C. 553; Federal Power Act, 16 U.S.C. 791-828c, as amended; Natural Gas Act, 15 U.S.C. 717-717w, as amended; Natural Gas Policy Act of 1978, 15 U.S.C. 3301 *et seq.*; Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2601 *et seq.*, as amended.

4. In § 375.206, paragraph (f)(2) is revised to read as follows:

§ 375.206 Procedures to close meetings.

* * * * *

(f) *Public availability of transcripts, records, minutes.* * * *

(2) The determination of the Director of the Division of Public Information to withhold information pursuant to paragraph (f)(1) of this section may be appealed to the General Counsel or the General Counsel's designee, in accordance with § 388.107 of this chapter.

PART 388—[AMENDED]

5. The authority citation for Part 388 continues to read as follows:

Authority: 5 U.S.C. 552 and 533.

6. In § 388.107, paragraph (a)(1) is amended by removing the word "Chairman" and inserting, in its place, the words "General Counsel or General Counsel's designee".

7. In § 388.107, paragraph (b) is revised to read as follows:

§ 388.107 Timetables and procedures in event of withholding public records.

* * * * *

(b)(1) The General Counsel or the General Counsel's designee will make a determination with respect to any appeal within 20 days after the receipt of such appeal. If, on appeal, the denial of the request for records is in whole or in part upheld, the General Counsel or the General Counsel's designee will notify the person making such request of the provisions for judicial review of that determination.

(2) Appeals filed pursuant to this section must be in writing, addressed to the General Counsel of the Commission, and clearly marked "Freedom of Information Act Appeal." Such an appeal received by the Commission not addressed and marked as indicated in this paragraph will be so addressed and marked by Commission personnel as soon as it is properly identified and then will be forwarded to the General Counsel. Appeals taken pursuant to this paragraph will be considered to be received upon actual receipt by the General Counsel.

* * * * *

[FR Doc. 87-2637 Filed 3-12-87; 8:45 am]
BILLING CODE 6717-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

[T.D. 87-29]

Country of Origin Marking of Certain Unfinished Sweaters; Change of Position

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final interpretative rule.

SUMMARY: This document gives notice that Customs is rescinding its previous rulings that New Zealand is the correct country of origin of sweaters made by sending New Zealand yarn to the People's Republic of China where it was knitted into sweater parts, which were partially sewn together and then returned to New Zealand where they were finished by completing the sewing and subjecting the garments to a process called "Super Wash".

After reviewing the comments received in response to the notice proposing this change, as well as the applicable law and judicial decisions, Customs now believes that the completion of the sewing and the "Super Wash" process do not result in a substantial transformation of the partially completed garment. Therefore, without a substantial transformation, the country of origin of the sweaters is the People's Republic of China, not New Zealand and the sweaters must be so marked.

EFFECTIVE DATE: This ruling shall be effective as to merchandise entered, or withdrawn from warehouse, for consumption on or after June 11, 1987.

FOR FURTHER INFORMATION CONTACT: Phil Robins, Classification and Value Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229 (202-566-8181).

SUPPLEMENTARY INFORMATION:

Background

Section 304 of the Tariff Act of 1930, as amended (19 U.S.C. 1304), provides that all articles of foreign origin, or their containers, imported into the U.S., shall be legibly and conspicuously marked to indicate the English name of the country of origin to an ultimate purchaser in the United States, unless specifically exempted. Part 134, Customs Regulations (19 CFR Part 134), sets forth the country of origin marking requirements. Section 134.1(b), Customs Regulations (19 CFR 134.1(b)), defines "country of origin" as the country of manufacture, production or growth of any article of foreign origin entering the U.S. Further work or material added to an article in a second country must effect a substantial transformation in order to render that country the "country of origin" within the meaning of 134.1(b).

The importance of determining an article's correct country of origin lies not only in informing the ultimate purchaser, but also in the effect it has on any import quota that may pertain to that article. An import quota is a quantity control system, usually based on bilateral agreements with the countries concerned, which limits the amount of certain merchandise that may enter the U.S. from a foreign country. Quotas vary according to the country from which the merchandise is exported, and the specific type of merchandise involved.

An article which enters the U.S. marked with the wrong country of origin may be incorrectly charged to that country's import quota. The incorrectly marked articles may cause the quota for that country to fill faster than it should, resulting in fewer articles entering the U.S. from the exporting country than would otherwise be permitted. Conversely, more articles than the quota permits may enter the U.S. from the actual country of origin. Wool sweaters which are the product of the People's Republic of China are subject to quota restraints agreed upon in a bilateral agreement between that country and the U.S., but wool sweaters which are the product of New Zealand are not subject to quota restraints.

The finishing process used by New Zealand sweater producers on sweaters they export to the U.S. has aroused a controversy concerning the sweaters' correct country of origin. These producers purchase raw New Zealand wool and have it spun into yarn and dyed in New Zealand. They then send the yarn on consignment to the People's Republic of China where it is knitted into sweater parts, namely the fronts, backs and sleeves, which are joined together at the shoulders. The partially joined parts are returned to New Zealand to be finished into sweaters by sewing the two side seams, each of which extends through the armpit area and along the sleeve to the sleeve end; being subjected to a proprietary process called "Super Wash;" and when

specifications so require, adding buttons, zippers, shoulder pads, elbow pads, etc.

It is Customs understanding that the function of the "Super Wash" process is to chemically treat the wool material so that the finished garment may be cleaned in a household washing machine. "Super Wash" is also supposed to assist in the sizing of the garment, and give it a softer touch, lighter color and greater durability than it would otherwise have had had it not undergone this process.

In Customs Ruling (CR) #719580 dated June 15, 1982, and in CR #716351, dated July 20, 1981, the issue before Customs was whether the importer's process of sewing, "Super Washing" and otherwise finishing the sweaters in New Zealand effected a substantial transformation of the sweater from unfinished parts into a finished garment. Without a substantial transformation, the country where the parts were originally produced and partially joined is the country of origin, not New Zealand where the sweater was completed. Customs held that the completion of the sewing, "Super Washing" and other finishing in New Zealand, was, in fact, a substantial transformation.

The U.S. Department of Commerce has requested that Customs reconsider these rulings on the basis that the completion of the sewing and the "Super Wash" processing do not result in a substantial transformation. Commerce believes that New Zealand is not the correct country of origin and as a result, these incorrectly marked sweaters are entering the U.S. free of the textile import quotas imposed on sweaters of Chinese origin. In view of the concern of the Commerce Department, Customs, by a notice published in the **Federal Register** on January 30, 1984 (49 FR 3671), determined that a review of the above rulings was warranted and invited public comments on them before any change was made.

Discussion of Comments

Twenty comments were received in response to the notice, ten favored rescinding Customs previous rulings, ten opposed. Those in favor argue that the operations performed in New Zealand do not effect a substantial transformation of what is essentially a Chinese garment. They state that a minor assembly and a finishing operation in an intermediate country does not constitute a substantial transformation. In support of their position, these commenters cited several Customs rulings and court cases, among them *Uniroyal Inc.* v. *United States*, 542 F. Supp. 1026 (C.I.T. 1982), *aff'd* 702 F. 2nd 1022 (C.A.F.C. 1982), in which the U.S. Court of International Trade held that, for country of origin marking purposes, Indonesian footwear uppers were not substantially transformed in the U.S. by domestic processing which included attachments of outsoles to the imported uppers. The court noted that the footwear uppers had already attained their ultimate shape, form, and size in Indonesia, and that the domestic addition of the outsole was a relatively minor operation.

By analogy, it was stated that each of the four sweater sections (front, back, right sleeve, left sleeve) is precisely knit in China to constitute an integral part of a predetermined shaped and sized sweater and that this, combined with the joining of the parts in China, creates a substantially complete sweater. Furthermore, the partial assembly in China is accomplished by looping the parts together at the shoulder and neck on a "looping" machine operated by a highly skilled worker. In contrast, the final seaming in New Zealand is performed on a "cup seaming" machine which is not as sophisticated as a "looping" machine and is an operation which requires substantially less skill.

Also cited is the case of *United States* v. *100 Pieces, More or Less, Style 200 Artificial Knees*, 283 F. Supp. 409 (C.D. Calif. 1968), in which East Germany was held to be the country of origin of artificial knees originating in East Germany, but shipped to Switzerland for finishing and minor assembly operations. The court held that no substantial transformation occurred in Switzerland.

The Customs rulings on the issue that have been cited in favor of rescinding these rulings include: CR #710564 (assembly of ceiling fan components held not to effect substantial transformation where assembly process was perfunctory and more in the nature of a combining process); CR #712545 (alteration of an already finished sewing machine held not to be a substantial transformation); CR #710586 (cutting, sewing, and finishing of piece goods into terry cloth towels will effect a substantial transformation, but sewing of pre-cut towels will not); CR #056570 (assembly of sandals in Hong Kong from parts from Taiwan did not result in Hong Kong sandals where all parts necessary to complete the sandal were produced in Taiwan). It is pointed out that no new components are added in New Zealand and that all the parts necessary to complete the sweaters are produced in China.

On the question of the "Super Wash" chemical treatment performed in New Zealand, the Supreme Court decision of *Anheuser-Busch Brewing Ass'n* v. *United States*, 207 U.S. 556, 28 S.Ct. 204 (1908), has been cited for the proposition that, in order for a substantial transformation to occur, a new and distinctive article must emerge having a new name, character, or use. In that decision, the Court rejected the claim that corks, subjected to a special (secret) chemical processing, were substantially transformed. A cork put through the claimant's process, the Court observed, is still a cork. Throughout the years, courts have held that various chemical treatments did not work a fundamental change in an article: *Howard Hardy & Co. Inc.* v. *United States*, T.D. 48441 (Cust. Ct. 1936), where "imperial finishing," a shrinkage process, did not cause a substantial transformation; *Amity Fabrics Inc.* v. *United States*, 43 Cust. Ct. 64, C.D. 2104 (1959), which held that dyeing a dyed fabric did not create a new article and, therefore, was a mere alteration; and *John J. Coates* v. *United States*, 3 Cust. Ct. 193, C.D. 232 (1939), where dyeing dresses was held not be a substantial transformation.

To further strengthen their position, the commenters in favor of rescission cited section 308 of the Trade Agreements Act of 1979 (19 U.S.C. 2518) which contains the Rule of Origin which further defines the substantial transformation test, the crucial concept upon which this case turns. In this statute, it is stated that "An article is a product of a country or instrumentality only if . . . in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed." The commenters pointed out that this rule was designed to prevent the evasive practice of transshipment through an intermediate country where minor processing may occur. Finally, it was also stated that under Department of Commerce export classification procedures, garment parts are tantamount to the article itself.

The commenters opposing any change in Customs current position argue that a substantial transformation occurs in New Zealand and cite several recent decisions of the U.S. Court of International Trade as well as several recent Customs rulings to support their position.

One case cited several times by opposing commenters was *Cardinal Glove Co., Inc.* v. *United States*, 4 C.I.T. 41 (1982). In *Cardinal Glove*, the court

determined that cotton gloves assembled in Haiti from front and back panels manufactured in Hong Kong did not require an export license (visa) from Hong Kong because Haiti was the country of exportation. The court also made a finding, although possibly dictum, that the assembly in Haiti constituted a substantial transformation of the merchandise.

Also cited is the subsequent decision of the Court of International Trade in *Belcrest Linens* v. *United States*, Slip Op. 83–107 (1983), in which the court held a pillowcase to be a product of Hong Kong, the country where Chinese fabric was cut at predetermined markings, scalloped, sewed, and hemmed. As it did in *Cardinal Glove*, the court decided the case on a country of exportation principle. In addition, the court indicated that the Chinese fabric underwent a substantial transformation in Hong Kong.

It is urged that the processing of the sweater parts in New Zealand clearly exceeds in degree the processing considered in *Cardinal Glove* and *Belcrest Linens* and that the subject finished sweaters are new and different articles of commerce as opposed to sweater parts. As one commenter points out, knitted pieces cannot be called sweaters, used as sweaters, or sold as sweaters. The identity of sweaters is conferred in New Zealand, not China.

One of the commenters notes that the original wool used to knit the sweater parts in China is derived from New Zealand sheep, spun into yarn and dyed in New Zealand. In fact, as another commenter points out, New Zealand has more to do with production of the sweaters than China from a cost analysis perpective, *i.e.*, 65 percent of the value of the sweater is claimed to be added in New Zealand, including the cost of the New Zealand wool (50 percent if the cost of the wool is excluded). Only 35 percent of the value of the sweater is said to be attributable to knitting of the sweater shapes in China. According to *United States* v. *Murray*, 621 F.2d 1163 (1st Cir. 1980), enhancement of value is a key element in deciding whether a substantial transformation has occurred. The *Murray* case was also cited by commenters favoring the change of practice. Appropriately enough, commenters opposing the change also cited the Supreme Court case of *Anheuser-Busch* for the proposition that if processing of an article occurs in two or more countries, the article is considered for tariff purposes to be a product of the last country in which the processing created a new and different article.

The commenters opposed to the change also cite recent Customs decisions to the effect that assembly of a garment constitutes a substantial transformation. For instance, C.S.D. 80–10 (CR #059089) held that Hong Kong was the country of origin of five or six Taiwanese separate sweater parts shipped to Hong Kong for assembly into a completed garment. It is also contended that C.S.D. 83–88 (CR #071303) held that the country of origin of cardigan sweaters was Guam where there was an assembly of five imported parts (including front panels attached to the rear panel at the shoulders).

On the issue of the "Super Wash" chemical treatment performed in New Zealand, one commenter describes this shrink-proofing process as a chemical polymer treatment which changes the physical nature of the garment to make it machine-washable. The "Super Wash" process adds a polymer film to coat the wool fibers, thus achieving inter-fiber bonding or resin bridges which limit or eliminate movement of the fibers relative to each other. Apparently, the "Super Wash" label can only be used if the international standards set by the International Wool Secretariat for dimensional stability, felting resistance, and colorfastness are met.

Another commenter points out that "Super Washing" converts the sweater shapes into sized articles of clothing. During "Super Wash" the shapes shrink about 3 inches lengthwise, but are thereafter stabilized against further shrinkage. Thus, the parts produced in China are not sized into a finished garment until "Super Washed" in New Zealand.

Some commenters cite the case of *Dolliff & Company Inc.* v. *United States*, 81 Cust. Ct. 1, C.D. 4755 (1978), in which the court found that fabric exported to Canada was not merely altered, but transformed into a new and different article when the processing performed in Canada included heat-setting, chemical-scouring, dyeing, and treatment with finishing chemicals for anti-creasing and anti-static characteristics.

One commenter points out that if "Super Washing" *alone* does not effect a substantial transformation, then surely "Super Wash" combined with assembly operations in New Zealand results in a substantial transformation.

The claim is made that not only is New Zealand the "country of origin" of the subject sweaters for marking purposes, but also the "country of exportation" for purposes of determining whether the sweaters are subject to the textile restraints imposed upon Chinese sweaters.

One commenter opposing the change of position states that country of origin determinations should be made independently of quota considerations and that the Commerce Department has no authority to interfere with Customs administration of Customs laws. Another commenter, in the same vein, states that country of origin determinations must be made under Customs laws as provided in the bilateral trade agreements. Still another commenter criticizes the Commerce Department for attempting to impose quota restraints upon New Zealand.

Finally, some commenters opposed to a change of position point out that Customs is required to reverse a practice only if such practice is "clearly wrong." Reference has been made to §§ 177.9(d)(2) and 177.10(b), Customs Regulations (19 CFR 177.9(d)(2), 177.10(b)), regarding the publication of ruling revocations.

Decision

First, it should be made clear that decisions of Customs, particularly rulings, are made after consideration of all relevant matters. Country of origin determinations in regard to marking and other areas are made on the facts of each case and what is deemed to be the applicable law. The quota status of merchandise is not a pertinent consideration. The views of the Department of Commerce concerning the correctness of a Customs ruling will be considered just as the views of any importer or manufacturer also would be considered.

Customs believes that the mere stitching together of two seams of an otherwise assembled sweater will not, by itself, cause a change in the country of origin of that garment. However, the problem is whether there has been a substantial transformation of the garment when the seam stitching is done in conjunction with other processing such as "Super Washing".

Whether a substantial transformation has occurred depends upon a comparison of the article *before* the processing which is claimed to effect such transformation and the article *after* the processing. Examination of the processing operations, and their relative costs and complexities, will also be considered. It is a well-settled principle of Customs law that, in order for a substantial transformation to be found, a new article having a new name, character, or use, must emerge from processing in a second country. *United*

States v. *Gibson-Thomsen Co. Inc.*, 27 C.C.P.A. 267, C.A.D. 98 (1940).

The *Dolliff* case, *supra*, is not applicable to the instant circumstances. The Court of Customs and Patent Appeals (*Dolliff & Co.* v. *United States*, 66 CCPA 77, C.A.D. 225 (1979)), decided the case on the narrow issue of whether the finishing, including heat setting and dyeing, of greige fabric, constituted an "alteration" for purposes of item 806.20, TSUS, not whether there was a substantial transformation for country of origin marking purposes.

Even if the CCPA decision in *Dolliff* could be extended beyond item 806.20, TSUS, that case does not go as far as *Joshua Hoyle & Sons* v. *United States*, 25 CCPA 128, T.D. 49244 (1937), which held that griege cloth which was mercerized and bleached became a new and different article having a new name, character, or use, because the processing transformed fabric which was commercially unsuitable for making shirts into shirting material.

United States v. *Murray*, *supra*, contains pertinent observations concerning country of origin criteria. There, the court defined the term "substantial transformation" as meaning a fundamental change in the form, nature, appearance, or character of an article which adds to the value of the article an amount or percentage which is significant in comparison with the value which the article had when exported from the country in which it was first manufactured, produced, or grown.

In regard to that definition, Customs does not believe that the sewing of two seams of a sweater and subjecting that garment to a "Super Washing" process *fundamentally* changes the form, nature, appearance, or character of that garment. If, instead of being sent to New Zealand for finishing, the sweater was to be finished in the U.S., upon its importation it would be considered to be a substantially complete sweater, and classified as such. See General Headnote 10(h), TSUS. The processing of the garment in New Zealand has not changed the essence of the article. *Uniroyal Inc.* v. *United States*, *supra*. In this connection, *United States* v. *American Textile Engineering, Inc.*, 26 CCPA 48, T.D. 49597 (1938), involved a texturing-type processing of yarn, and, while the court recognized that the processing advanced the yarn in condition for use and to some extent changed its characteristics, the court held the merchandise did not have a new name, character, or use. The resultant product was still yarn.

Pursuant to the decisions in *Murray* and *Uniroyal*, the relative values and costs and the complexity of processing may be compared to aid in the determination of whether there has been a substantial transformation of the merchandise in a second country. Neither of those cases dealt with a situation such as presented here, where material from New Zealand is clearly transformed by a substantial manufacturing process into a product of China before being returned to New Zealand for further processing. What left China was plainly a product of that country. Therefore, it is logical to compare what left China with what was entered into the U.S. to determine if there has been sufficient further processing in New Zealand for the merchandise to cease being a Chinese product. Following the wording of *Murray*, it would appear that the initial costs and processing incurred in New Zealand *may* be attributable to China. However, in view of the fact that there was no fundamental change in the merchandise in New Zealand prior to its export to the U.S., it is not necessary to resolve the allocation, if any, of the initial New Zealand costs and processing.

The decision in *Cardinal Glove*, *supra*, involved a completely different factual situation and is not considered controlling. That case involved the assembly of glove halves and was decided essentially on a country of exportation principle. Although making a finding of substantial transformation, at no time did the court discuss or review the legal principles involved with that principle.

It should also be noted that, contrary to an assertion that *Cardinal Glove* expressly approved of the result in C.S.D. 80–10, the court only cited the holding. The court expressed its full agreement with that portion of C.S.D. 80–10 which held that the manner of shipment from one country to a second country is not relevant to the determination of which country is the country of exportation.

After the receipt of comments requested on this matter, by T.D. 84–171, published in the **Federal Register** on August 3, 1984 (49 FR 31248), Customs issued interim regulations, which set out in § 12.130, Customs Regulations (19 CFR 12.130), criteria for country of origin determinations of textiles and textile products for quota, visa, and export license purposes. Numerous comments were received in response to the interim regulations. After consideration of the comments and further review of the matter, by T.D. 85–38, published in the **Federal Register** on March 5, 1985 (50 FR 8710), Customs adopted the interim regulations with certain modifications. Section 12.130, provides that where an article is the growth, product, or manufacture of two or more countries, it is a product of that country where it was substantially transformed by means of a substantial manufacturing or processing operation into a new and different article of commerce. Specific criteria are set forth to be considered in determining (1) whether there has been a substantial manufacturing or processing operation, and (2) whether, prior to importation into the U.S., an article or material usually will or will not be considered a product of a particular foreign territory or country, or insular possession of the U.S. Specifically stated not to constitute a substantial transformation are such processes as the mere joining together of otherwise completed component parts and "Super Washing". However, by performing both of these operations in one country, a substantial transformation is not automatically precluded.

Although § 12.130 was specifically promulgated for quota, visa, and export license purposes, the principles of origin contained therein were derived from recent judicial decisions (*e.g.*, *Uniroyal* v. *United States*) and represent the law, as Customs understands it, to be applied in all country of origin decisions.

While, on their face the new regulations may appear to be in conflict with *Cardinal Glove*, *supra*, and such administrative decisions as C.S.D. 80–10, Customs does not believe that this is the case. If the court in *Cardinal Glove*, or if Customs in C.S.D. 80–10 and other rulings, had the information available which is now required by §12.130, concerning costs and complexity of processing, etc., and had considered that information, as the court did in *Uniroyal*, the results could have been different.

Customs believes that when a comparison is made between the unfinished sweaters which went into New Zealand and the completed sweaters which were exported from New Zealand, the stitching and "Super Washing" in New Zealand actually amounted to a minor processing.

Accordingly, whether following the recent decisions in *Murray* or *Uniroyal* or the origin principles embodied in § 12.130, Customs believes that the sewing of two seams and the treating of a sweater so that it is washable does not fundamentally change a substantially complete sweater into a new and different article having a new name, character, or use. Therefore, this document revokes both CR #716351 and CR #719580 and any other existing Treasury or Customs decisions or administrative rulings, to the extent that

they are inconsistent with the views contained herein.

In a related matter, by a document published in the **Federal Register** on August 2, 1985 (50 FR 31392), Customs proposed to change the established and uniform practices that are in conflict with the new criteria set forth in § 12.130. Because these changes of practice, if adopted, may result in higher rates of duty being assessed, the notice invited public comments on them before any change is made. After analysis of comments received in response to the notice proposing the changes of practice, another document will be prepared for publication in the **Federal Register**.

Drafting Information

The principal author of this document was Glen E. Vereb, Regulations Control Branch, Office of Regulations and Rulings, Customs Headquarters. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 134

Customs duties and inspection, imports, labeling, packaging and containers.

William von Raab,

Commissioner of Customs.

Approved.

Michael H. Lane,

Acting Assistant Secretary of the Treasury.

June 24, 1986.

Editorial Note.—This document was received at the Office of the Federal Register March 10, 1987.

[FR Doc. 5418 Filed 3–12–87; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Drugs and Biologics Officials

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FRA) is amending the regulations for delegations of authority to terminate exemptions for new drugs for investigational uses when sponsors fail to submit an annual progress report under 21 CFR 312.1(d)(10). This amendment will delegate authority to those division directors and deputy division directors in the Center for Drugs and Biologics (CDB) who are already authorized under 21 CFR 5.71(a)(2) to take certain pretermination actions.

EFFECTIVE DATE: March 13, 1987.

FOR FURTHER INFORMATION CONTACT: Marjorie J. Shandruk, Office of Management and Operations (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: FDA is revising § 5.71 *Termination of exemptions for new drugs for investigational use in human beings and in animals* (21 CFR 5.71) by redesignating existing paragraph (a)(1)(ii) as paragraph (a)(1)(iii) and adding new paragraphs (a)(1) (ii) and (iv). In order to facilitate efficiency in the routine termination of investigational new drugs whose sponsors have failed to submit annual progress reports, this authority is delegated to the following Center for Drugs and Biologics officials: Directors and Deputy Directors in the Divisions of Neuropharmacological Drug Products, Cardio-Renal Drug Products, Surgical-Dental Drug Products, and Oncology and Radiopharmaceutical Drug Products in the Office of Drug Research and Review; Directors and Deputy Directors in the Divisions of Anti-Infective Drug Products, and Metabolism and Endocrine Drug Products in the Office of Biologics Research and Review.

Further redelegation of the authority is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552; 7 U.S.C. 2217; 15 U.S.C. 638, 1451 et seq.; 21 U.S.C. 41 et seq., 61–63, 141 et seq., 301–392, 467f(b), 679(b), 801 et seq., 823(f), 1031 et seq.; 35 U.S.C. 156; 42 U.S.C. 219, 241, 242(a), 242a, 242l, 242o, 243, 262, 263, 263b through 263m, 264, 265, 300u et seq., 1395y and 1395y note, 3246b(b)(3), 4831(a), 10007, and 10008; Federal Caustic Poison Act (44 Stat. 1406); Federal Advisory Committee Act (Pub. L. 92–463); E.O. 11490, 11921.

2. Section 5.71 is amended by redesignating existing paragraph (a)(1)(ii) as paragraph (a)(1)(iii) and by adding new paragraphs (a)(1) (ii) and (iv), to read as follows:

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) * * *

(1) * * *

(ii) The Directors and Deputy Directors of the Divisions of: Neuropharmacological Drug Products, Cardio-Renal Drug Products, Surgical-Dental Drug Products, and Oncology and Radiopharmaceutical Drug Products, Office of Drug Research and Review, CDB.

* * * * *

(iv) The Directors and Deputy Directors of the Divisions of: Anti-Infective Drug Products, and Metabolism and Endocrine Drug Products, Office of Biologics Research and Review, CDB.

* * * * *

Dated: March 6, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5383 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 74

[Docket No. 85C–0377]

[Phthalocyaninato(2-)] Copper; Listing as a Color Additive for Coloring Contact Lenses; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confiming the effective date of November 28, 1986, for the final rule that amended the color additive regulations to delete the current limitation on the level of [phthalocyaninato(2-)] copper to color contract lenses.

EFFECTIVE DATE: Effective date confirmed: November 28, 1986.

FOR FURTHER INFORMATION CONTACT: Mary J. Stephens, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 1986 (51 FR 39370), FDA amended 21 CFR Part 74 of the color additive regulations in 21 CFR 74.3045 by revising paragraph (c)(2) to eliminate the 0.01 percent limitation

in the use of [phthalocyaninato(2-)] copper in contact lenses.

FDA gave interested persons until November 28, 1986, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA had concluded that the final rule published in the **Federal Register** of October 28, 1986, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the October 28, 1986, final rule. Accordingly, the amendments promulgated thereby became effective November 28, 1986.

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–5446 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 331, 332, and 357

[Docket No. 82N–0154]

Labeling of Drug Products for Over-The-Counter Human Use; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that changed its "exclusivity" policy for labeling of over-the-counter (OTC) drug products. This document indicates that specific paragraphs in 21 CFR 331.130(b), 332.30(a), and 357.250(b) where other statements describing indications for use are located. By indicating these specific paragraphs, FDA will eliminate the ambiguity associated with the use of the term "above".

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug and Biologics (HFN–210), Food and Drugs Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–9720, appearing on page 16258 in the issue of Thursday, May 1, 1986, the following corrections are made:

§ 331.30 [Corrected]

1. On page 16266, in the third column under § 331.30 *Labeling of antacid products*, paragraph (b), 14th line, "above" is corrected to read "in this paragraph (b)".

§ 332.30 [Corrected]

2. On page 16266, in the third column under § 332.30 *Labeling of antiflatulent products*, paragraph (a), 9th line, "above" is corrected to read "in this paragraph (a)".

§ 357.250 [Corrected]

3. On page 16267, in the second column under § 357.250 *Labeling of cholecystokinetic drug products*, paragraph (b), 9th line "above" is corrected to read "in this paragaph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5382 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 341

[Docket No. 75N–052B]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Bronchodilator Drug Products; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) bronchodilator drug products (drug products used in the symptomatic treatment of wheezing and shortness of breath of asthma) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 341.76(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "below."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–22151, appearing on page 35326 in the issue of Thursday, October 2, 1986, the following correction is made on page 35339: In the third column under § 341.76 *Labeling of bronchodilator drug products*, paragraph (b), 8th line, "below" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5380 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 344

[Docket No. 77N–0334]

Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) topical otic drug products (drug products for the ear) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 344.50(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "above."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–17854, appearing on page 28656 in the issue of Friday, August 8, 1986, the following correction is made on page 28661: In the second column under § 344.50 *Labeling of topical otic drug products*, paragraph (b), 10th line, "above" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5381 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 357

[Docket No. 79N–0378]

Anthelmintic Drug Products for Over-The-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.