

ATTACHMENT 2

information on the hearing will hold concerning this ANPR.

B. Public Participation Funds Available. Because public participation in this rulemaking can reasonably be expected to promote a full and fair determination of the issues involved, NOAA has made available \$5,000 to compensate participants in the rulemaking who meet the eligibility criteria of NOAA regulations governing "Financial Compensation of Participants in Administrative Proceedings" (15 CFR Part 904). For further information concerning the availability of these public participation funds, see NOAA's announcement at 45 FR 70475 (Friday, October 24, 1980). As specified in that earlier announcement, applications to receive part or all of this public participation fund must be received by NOAA on or before November 24, 1980.

VI. Rulemaking by Other Federal Agencies

NOAA advises interested persons that other Federal agencies also may be issuing regulations to carry out new responsibilities under the Act. Agencies that may be conducting OTEC-related rulemaking may include: the Coast Guard (see section 108, section 109(c), and section 303(a)); the Environmental Protection Agency (see section 101(c)(4), and section 107(f)); and the Maritime Administration (see Title II of the Act).

VII. Authority

This advance notice of proposed rulemaking is issued under authority of section 102 of the Act.

Signed this 18th day of November 1980.

Samuel A. Lawrence,

Assistant Administrator for Management and Budget.

[FR Doc. 80-36356 Filed 11-20-80; 8:45 am]

BILLING CODE 3510-12-M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Ch. I

Contract Market Rules and Practices Governing the Imposition and Maintenance of Price Limits; Extension of Comment Period

AGENCY: Commodity Futures Trading Commission.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: On August 20, 1980, the Commission's advance notice of proposed rulemaking regarding the imposition and maintenance of price

limits by contract markets was published in the *Federal Register* (45 FR 55469). The comment period thereon expires on November 18, 1980.

The Commission has received requests for an extension of the comment period. Because the Commission wishes to be certain that all parties have an adequate opportunity to finalize and submit their comments, it is allowing an additional thirty days for comment.

DATES: Notice is hereby given that all comments must be submitted by December 18, 1980.

ADDRESS: Interested persons should submit comments to: Commodity Futures Trading Commission, 2033 K Street, NW., Washington, D.C. 20581, Attn: Office of the Secretariat, (202) 254-6314.

FOR FURTHER INFORMATION CONTACT: Christine A. Rock, Attorney Advisor, Division of Trading and Markets, (202) 254-8955.

Issued in Washington, D.C., on November 18, 1980.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 80-36466 Filed 11-20-80; 8:15 am]

BILLING CODE 6351-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 260

[Docket No. RM80-69]

Revision of Annual Report of Gas Supply For Certain Natural Gas Pipelines; Form No. 15; Meetings

Issued November 17, 1980.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of public meetings.

SUMMARY: On November 6, 1980, the Federal Energy Regulatory Commission (Commission) issued an Interim Rule amending Form No. 15, "Annual Report of Gas Supply for Certain Natural Gas Pipelines," to eliminate reporting requirements which the Commission no longer needs to carry out its regulatory functions (Docket No. RM80-69, 45 FR 75192, November 14, 1980). In that rule the Commission stated that a series of informal meetings with Commission staff would be held to discuss the proposed revisions to the format, instructions and definitions of Form No. 15. The meetings will be held December 2, 9, and 16 in Washington, D.C.

DATES: December 2, 1980 at 10:00 a.m., December 9, 1980 at 10:00 a.m., and December 16, 1980 at 10:00 a.m.

ADDRESS: Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 9306, Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Wayne Thompson, Chief, Gas Supply Branch, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 4402B, Washington, D.C. 20426, (202) 357-9077.

SUPPLEMENTARY INFORMATION: Among items for discussion at these meetings are: (1) redesigning the form to better facilitate human (non-computer) use; (2) standardizing the definitions to conform with those used in other Commission reporting requirements; (3) revising the instructions to comply with changes resulting from passage of the Natural Gas Policy Act of 1978 (15 U.S.C. §§ 3301-3432); (4) examining the need for, and alternatives to, individual reservoir reports; and (5) discussing the possibility of additional supply reporting in the form.

A general discussion of Form No. 15 revisions is scheduled for the December 2nd meeting. The definitions, instructions and redesign of the form will be analyzed at the December 9th meeting. Data automation for the form will be examined at the December 16th meeting. Other relevant questions concerning revisions to Form No. 15 will also be entertained.

If subsequent meetings are necessary, they would take place in January, 1981, in Washington, D.C. Notice of such meetings would be published after the December 16th meeting. Transcripts of the meetings will be placed in the public record, and will be available from the Commission's Office of Public Information.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-36321 Filed 11-20-80; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 70

[Docket No. 79P-0077]

Nitrites in Bacon; Proposed Exception From the Color Additive Definition and Request for Information on Other Meat Products That May Qualify for the Exception to the Color Additive Definition

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Food and Drug Administration (FDA) concludes that nitrites in bacon are not "color additives" under the Federal Food, Drug, and Cosmetic Act because nitrites do not "impart" color to bacon within the meaning of the statutory definition of "color additive." Based on this conclusion, it is no longer necessary for FDA to consider whether nitrites qualify for the exception to the "color additive" definition for substances used solely for noncoloring purposes. FDA's conclusion constitutes final agency action on issues raised in a citizen's petition that asked FDA to regulate nitrites in bacon as "color additives."

EFFECTIVE DATE:
December 22, 1980.

FOR FURTHER INFORMATION CONTACT:
John L. Herriman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:**I. Background**

In the Federal Register of December 21, 1979 (44 FR 75659), FDA issued a notice of proposed rulemaking in which it proposed to adopt certain new positions relating to the status of nitrites in bacon and other red meats under the color additive provisions of the Federal Food, Drug, and Cosmetic Act (the act). As used in that proposal and in this document, the term "nitrites" includes sodium and potassium nitrate and sodium and potassium nitrite.

The question of nitrites' status as "color additives" was presented initially to FDA on March 12, 1979, in a citizen petition filed jointly by Public Citizen, Inc., and four others (Ref. 1—44 FR 75662; December 21, 1979). The citizen petition asked FDA to declare that nitrites in bacon are "color additives" within the meaning of section 201(t)(1) of the act (21 U.S.C. 321(t)(1)) that may not be used until approved by FDA under the color additive provisions of the act (21 U.S.C. 376).

FDA responded to the citizen petition by letter on June 29, 1979 (Ref. 2—44 FR 75662; December 21, 1979). In that letter, FDA stated its tentative conclusions that: (1) nitrites in bacon are capable of "imparting color" within the meaning of section 201(t)(1) of the act, but (2) nitrites are not properly regulated as "color additives" because they qualify for the exception in section 201(t)(1) of the act for substances determined by FDA to be "used (or intended to be used) solely for a purpose or purposes other than coloring." The

response to the citizen petition stated FDA's intention to initiate rulemaking to reach final conclusions on these questions.

As noted, FDA initiated the necessary rulemaking by publishing a proposal in the Federal Register on December 21, 1979 (44 FR 75659). The proposal explained that FDA's tentative conclusion that nitrites are capable of imparting color to bacon would, if made final, also apply to nitrites used in other red meat products. Thus, FDA included in the proposal a request for information on whether red meat products other than bacon also might qualify for the exception to the "color additive" definition. FDA allowed a 60-day comment period on the proposal and request for information. At the request of several industry groups and firms, FDA extended the comment period on the request for information to May 19, 1980 (see 45 FR 11841; February 22, 1980) and then indefinitely (45 FR 32324; May 16, 1980). FDA based the indefinite extension of the deadline on the request for information on the fact that information concerning possible exceptions to the "color additive" definition for nitrites in meats other than bacon would be needed only if FDA concludes finally that nitrites meet the threshold requirement for "color additive" status (i.e., are capable of imparting color). Because the expense required to collect the information would be wasted if FDA were to conclude that nitrites do not "impart" color, the agency agreed to defer the exception issue until after a final decision is reached on whether nitrites "impart" color. Although the comment period on the request for information was deferred, the comment period on whether nitrites "impart" color to bacon and other red meats and whether nitrites in bacon qualify for the exception to the "color additive" definition closed on February 19, 1980.

FDA received more than 150 comments on the proposal. The vast majority of the comments focused on whether nitrites are capable of "imparting" color and argued on scientific, legal, and policy grounds that FDA's tentative conclusion on this point was incorrect. FDA agrees that its tentative conclusion was incorrect and now concludes that nitrites do not "impart" color to bacon within the meaning of section 201(t)(1) of the act. The reasons for this conclusion are discussed below.

II. Discussion

The act defines the term "color additive" in section 201(t)(1), as follows:

(1)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substances) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

Under this definition, a substance added to food is a "color additive" if it is "capable . . . of imparting color" to the food, but color-imparting substances can be excepted from the definition if FDA (by delegation of authority from the Secretary) makes certain determinations about the purpose for which the substance is used. The threshold question of whether a substance is capable of "imparting color" obviously is of paramount importance: only if a substance "imparts" color must FDA consider whether it qualifies for the exception to the "color additive" definition.

The "color additive" definition was enacted by Congress as part of the Color Additive Amendments of 1960, which established a separate premarket approval system for color additives. A similar system had been in effect for food additives since the enactment of the Food Additives Amendment of 1958. Before enactment of the Color Additive Amendments, non-coal-tar colors added to food were regulated as "food additives," but the Color Additive Amendments amended the definition of the term "food additive" to exclude "color additives." Thus, in the months and years following enactment of the Color Additive Amendments, it was necessary for FDA to determine whether particular substances previously regulated under the "food additive" provisions of the act should be regulated instead as "color additives."

As many comments correctly point out, FDA's original determination with respect to nitrites was that they should continue under the "food additive" provisions of the act because the effect of nitrites in meat was merely to "fix" the color of the meat, not "impart" color. This original determination is reflected in FDA regulations promulgated as far back as 1962 in which sodium nitrite and sodium nitrate are specifically identified as "food additives" and are approved for use as preservatives and color fixatives (21 CFR 121.1063 and 121.1064 (27 FR 2090; March 3, 1962), since

recodified as 21 CFR 172.170 and 172.175 (recodification in the *Federal Register* of March 15, 1977; 42 FR 14302)). FDA has consistently throughout the years maintained its position that nitrites merely "fix" rather than "impart" color. The position is reflected in current FDA regulations (21 CFR 172.170 and 172.175) and has been asserted publicly by FDA in judicial proceedings. See *Public Citizen v. Foreman*, 471 F. Supp. 586, 593 (D.D.C. 1979). In addition, U.S. Department of Agriculture (USDA) regulations governing the use of nitrites describe the color effect of nitrites as a color "fixing" effect (see 9 CFR 318.7(c)(4)).

In response to the Public Citizen petition asking FDA to regulate nitrites in bacon as "color additives," FDA reconsidered its longstanding position that nitrites merely "fix" color. The citizen petition argued that nitrites "impart" color to bacon because when nitrites are added to bacon they combine with the myoglobin naturally present in red meat to form a substance that, when heated during the curing process, yields nitrosohemochrome (or nitrosylhemochrome), which is similar in color to fresh pork (pink) but makes the color last longer. The petition contended that no pork without nitrosohemochrome has the exact color of meat with it, but the petition also argued that it is irrelevant for purposes of the "color additive" definition whether a substance changes the color of food in a noticeable way.

By focusing almost exclusively on the details of the chemical reaction that occurs when nitrites are added to bacon, the Public Citizen petition appears to provide a plausible basis for concluding that nitrites "impart" color, and FDA tentatively adopted Public Citizen's position in its response to the citizen petition. In explaining its tentative conclusion that nitrites "impart" color, FDA described in its proposal the chemical reaction that occurs when nitrites are used in the curing of bacon (see 44 FR 75660; December 21, 1979). The agency noted that the color resulting from the use of nitrites in bacon is " * * * similar to, and sometimes nearly indistinguishable from, * * * the color of the freshly slaughtered meat. The agency tentatively concluded that nitrites "impart" color, however, because, after heating, meat without nitrites turns brown while meat with nitrites retains its pink color.

The majority of comments attack FDA's tentative conclusion on several grounds. On technical grounds, the comments argue that the true color-

imparting pigment in meat is myoglobin, which can be various shades of purple, red, pink, or brown depending on the compounds with which it interacts. They argue that the effect of nitrites is to maintain the myoglobin in a stable form that is red in color, noting correctly that the intensity of the red color in nitrite-treated meat is related directly to the concentration of the pigment, not the amount of nitrites added to the meat—once the pigment is stabilized by nitrites, the addition of more nitrites does not increase the intensity of the red color. Thus, these comments seem to argue, color is "imparted" to meat by a naturally occurring pigment; nitrites merely "fix" the pigment in a form that produces a stable, red color.

One comment included photographic evidence intended to show that there is no difference visible to the naked eye between the color of bacon cured with nitrites and the color of uncured pork belly (the portion of the hog from which bacon is produced) 1 day after slaughter. This comment cited a letter in the legislative history of the Color Additive Amendments from then Secretary of Health, Education, and Welfare (HEW) Flemming, which states that the HEW-drafted bill that became the Color Additive Amendments of 1960 was intended to cover substances whose coloring effect is "apparent to the naked eye" (H.R. Rep. No. 1761 at 79; 1960 U.S. Code, Cong. and Adm. News 2929). According to the comment, the comparison of the color of nitrite-cured bacon with that of uncured pork belly 1 day after slaughter is the critical comparison for the purpose of considering whether nitrites "impart" color because it is about 1 day after slaughter that the uncured pork belly would be displayed to consumers on the supermarket shelf. The comment argues that, because there is no visible difference at this point between the color of nitrite-cured bacon and uncured pork belly, nitrites do not "impart" color.

In addition to making these technical arguments, the comments point out that if FDA finally adopts its tentative conclusion that nitrites "impart" color, it will be changing a 20-year-old interpretation of the act without there being any new facts to justify a change. The comments are correct that the relevant scientific facts, i.e., the nature of the chemical reactions that occur when nitrites are added to meat, have not changed since the Color Additive Amendments were enacted in 1960, and there is no genuine dispute over what those reactions are. Thus, the issue of whether nitrites "impart" or merely "fix"

color turns on how the chemical reactions are characterized for the purpose of applying the "color additive" definition. This is largely a matter of statutory interpretation; and, the comments argue, the interpreter, given the statute by FDA officials immediately following its enactment is entitled to substantial deference. The comments argue further that, because the industry has relied on FDA's original interpretation for nearly 20 years, that interpretation should not be changed, especially in the absence of any significant new facts justifying a change.

Based on the comments it received, FDA concludes that its reconsideration of whether nitrites "impart" or merely "fix" color, which the agency undertook in response to the Public Citizen petition, focused too narrowly on the chemical reactions that occur when nitrites are added to bacon and other red meats and failed to give adequate weight to the practical meaning of the "color additive" definition and FDA's past interpretation of it. FDA concludes that its original and long-held position that nitrites in bacon merely "fix" rather than "impart" color reflects a sound and reasonable interpretation of the "color additive" definition. Nothing contained in Public Citizen's petition or in the comments on FDA's proposal justify a change in that interpretation.

FDA's original position that nitrites are not "color additives" is consistent with the practical approach Congress intended FDA to take in distinguishing "color additives" from other categories of substances added to food by food manufacturers and processors. As noted above, just 2 years before the enactment of the Color Additive Amendments, Congress had enacted the Food Additives Amendment of 1958, which established a premarket approval system for all substances (including colors) that are added to food by food processors and manufacturers, excepting only those substances that are generally recognized as safe, had already been approved by FDA or USDA, or were subject to an existing, adequate regulatory scheme, e.g., pesticide residues under the Pesticide Residue Amendment of 1954. Congress and HEW (the Department that drafted the bill) thus were aware when the Color Additive Amendments were under consideration that all substances intentionally added to food would be subject to acceptably rigorous regulatory standards whether regarded as "color additives" or not and that it was therefore unnecessary to make fine distinctions among substances based on such refined considerations as the

precise nature of the chemical reaction that occurs when a substance is added to food.

Illustrative of the practical approach Congress adopted for distinguishing "color additives" from other substances added to food is Secretary Flemming's explanation, noted briefly above, for why coloring materials used in food packaging would not ordinarily be "color additives," even if they migrate to the food:

[I]t is our view that the bill is intended to regulate substances that color or are capable of coloring food to a degree apparent to the naked eye. Thus, a component of food packaging that migrated into food but did not change its color in the ordinary sense of the term would continue to be regulated, if necessary, under the food additives amendment and would not become subject to the proposed color additives bill.

H.R. Report No. 1761, P. 79: 1960 U.S. Code, Cong. and Adm. News 2929 (emphasis added).

It also is clear from the legislative history that even substances that affect the color of food in readily apparent ways are not all considered "color additives." In responding to a concern expressed by the pesticide industry that certain pesticides might arguably fall within the proposed "color additive" definition, Secretary Flemming wrote the following to Congressman Oren Harris:

The second question relates to pesticide chemicals as defined in section 201(q) of the Federal Food, Drug, and Cosmetic Act. We are advised that certain fungicides used in fruit production have the effect not only of protecting the tree against plant diseases but also of affecting or supporting natural plant processes so the plant produces better color and finish in the fruit, and some plant growth regulators, when applied to plants, likewise enhance the development of normal color in produce derived from them.

It is our view that pesticide chemicals used in this way are not color additives within the meaning of the proposed legislation and do not impart an artificial color to the raw agricultural commodities. Rather, they promote the development of the natural color of produce as a result of the normal physiological processes of the plant. The legislation which we drafted was not intended to apply to pesticide chemicals which enhance color by affecting or supporting natural plant processes * * *.

Hearings on H.R. 7624 and S. 2197 Before the House Comm. On Interstate and Foreign Commerce, 86th Cong., 2nd Sess. 188-189 (1960) (letter from Arthur S. Flemming to Rep. Oren Harris), (emphasis added).

It is likely that one could trace the chain of chemical reactions that causally connect the pesticides discussed by Secretary Flemming and

the resulting color of the fruit, but that obviously is not what Congress intended FDA to do in applying the "color additive" definition. The legislative history, coupled with the use of the terms "dye" and "pigment" in the definition itself, suggest instead that Congress intended the term "color additive" to cover dyes, pigments, and similar substances that are ordinarily thought of as coloring agents.

Against this background, it is clear why the FDA officials responsible for the initial implementation of the Color Additive Amendments did not regard nitrites to be "color additives." Nitrites have been used as curing agents in modern meat processing since early in the century for their preservative, flavor, and color-fixative effects. During those years, the USDA regulations approving the use of nitrites have consistently described the coloring effect of nitrites as a color "fixative" effect and have explicitly distinguished between coloring agents per se (such as coal tar dyes) and curing agents, whose purposes include, inter alia, "fixation" of color. This distinction is maintained in USDA's current regulation (see 9 CFR 319.7(c)(4)).

When the Color Additive Amendments were enacted in 1960, FDA officials presumably did not scrutinize the chemical reactions that occur when nitrites are added to meat in order to determine whether nitrites were to be regarded as "color additives." They apparently relied instead on the traditional conception of nitrites not as "coloring agents" but as "curing agents" that accomplish a variety of processing purposes and that affect the color of meat in a way quite different from dyes, pigments, and other "coloring agents." As the comments on FDA's proposal demonstrate, nitrites do not add a new color to bacon, but instead react with the naturally occurring pigment in meat (myoglobin) to produce during the curing process a form of the pigment that is more stable. The color of the nitrite-cured bacon is not readily distinguishable, however, from the color of the uncured pork belly at or shortly after slaughter. On these grounds, it was reasonable for FDA officials not to regard nitrites to be "color additives" and to continue to regulate them under the more logically applicable Food Additives Amendment.

The grounds that apparently underlie FDA's original position that nitrites are not "color additives" remain sound. In the ordinary sense of the term, nitrites do not "impart" color; they merely "fix" the color naturally present in meat. It is a well-founded principle of statutory

construction that the agency's interpretation of its own statutes should be given great weight. *Public Citizen v. Foreman* (D.C. Cir. No. 79-1690, July 31, 1980). In this case, FDA hereby reaffirms the agency's longstanding interpretation.

In reaching its tentative conclusion that nitrites "impart" color, FDA relied in part on the fact that meat without nitrites turns brown after heating, while meat with nitrites retains its pink color. However, as a matter of common sense, preserving or "fixing" an existing color so that it does not change during heating is clearly not the same as "imparting" a new color. As shown by the legislative history discussed earlier, it is the addition of a visibly different, new color that makes a substance fall within the "color additive" definition. Substances that affect the color of food in other ways are regulated under other provisions of the act.

If, in applying the "color additive" definition, FDA were to take into account routinely the effects of heating (or cooking) on the color of processed foods, the task of determining whether substances are "food additives" or "color additives" would become extraordinarily complex and would produce surprising results. The heat to which foods are exposed during processing or cooking is sufficient to change the chemical composition, and thus possibly the color, of many substances both naturally present in and added to food. For example, sugar added to bakery products before cooking causes the finished products to have darker crusts than they otherwise would have. However, regardless of how one might describe the chemical reactions that occur, sugar and other substances that only affect the color of finished food articles as a result of changes in color that occur after exposure to heat during processing or home cooking are not the kind of substances Congress intended to regulate as "color additives." By taking a practical, common sense approach to distinguishing between "color additives" and other substances, FDA has been able to avoid wasteful disputes about the proper regulatory category for such substances and to implement the Color Additive Amendments and other food safety provisions of the law in a way that is consistent with both the intent of Congress and the protection of the public health.

As discussed earlier the majority of comments received argue in favor of FDA's final decision to consider nitrites as color fixatives and therefore not color additives. Comments also were received that argue that nitrites do in fact impart

color as originally proposed by the agency. FDA has considered these comments and rejects them for the reasons stated in this document. Still other comments state that while nitrites do indeed impart color, they qualify for the exception to the color additive law since they are used solely for purposes other than coloring. Since the agency rejects the premise of these comments that nitrites impart color, further consideration of their status under the color additive law is irrelevant and therefore has not been considered by the agency in reaching this decision. Lastly, there were several comments that did not substantively address the issue of whether nitrites "fix" or "impart" color. Rather they generally argued that the risks and benefits of nitrites should be considered in deciding their status. All but one of these comments urged the continued availability of nitrites in meat products. The purpose of this rulemaking is to determine whether nitrites used in meat products are color additives within the meaning of 21 U.S.C. 321(t). A risk/benefit analysis is not relevant to this consideration and, therefore, FDA has not considered these comments in reaching the decision that nitrites "fix" rather than "impart" color.

Based on its conclusion that nitrites do not "impart" color to bacon, FDA will not adopt as final regulations proposed § 70.70 *Capacity of nitrites in meat products to impart color* and § 70.100 *Nitrites in bacon*, which incorporated, respectively, FDA's tentative conclusions that nitrites "impart" color but that nitrites in bacon qualify for the statutory exception to the "color additive" definition (see 44 FR 75662). Those proposed regulations are hereby withdrawn. It also is unnecessary for FDA to consider further whether nitrites in meats other than bacon qualify for the exception to the "color additive" definition. FDA thus withdraws its request for information on that issue.

FDA's conclusion that nitrites "fix" rather than "impart" color to bacon constitutes final agency action in response to the Public Citizen petition asking FDA to regulate nitrites in bacon as "color additives."

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), (t)(1), 402(a), 701(a), 706, 52 Stat. 1048 as amended, 1055, 72 Stat. 1784 as amended, 74 Stat. 397-407 as amended (21 U.S.C. 321(s), (t)(1), 342(a), 371(a), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), the proposed regulations (44 FR 75659; December 21, 1979) are hereby withdrawn.

Dated: November 17, 1980.
Mark Novlitch,
Acting Commissioner of Food and Drugs.
(FR Doc. 80-36413 filed 11-20-80 8:45 am)
BILLING CODE 4110-03-M

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 2

General Provisions; Rule Making

AGENCY: Office of the Secretary, Labor.

ACTION: Proposed rule.

SUMMARY: It is proposed to rescind the regulation waiving the exemption to the Administrative Procedure Act (5 U.S.C. 553) for rules relating to public property, loans, grants, benefits or contracts. The rescission is necessary due to confusion that has arisen concerning applicability of APA requirements to matters which have not heretofore been regarded by the Department as "rules." The effect will be to allow the Department to use the exemption provided by Congress for information-gathering procedures.

DATES: Comments must be received on or before December 22, 1980.

ADDRESS: Comments must be in writing and should be sent to Sofia Petters, Counsel for Administrative Legal Services, Office of the Solicitor, U.S. Department of Labor, Room N2464, 200 Constitution Avenue NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Sofia Petters, Counsel for Administrative Legal Services, Office of the Solicitor, U.S. Department of Labor, Room N2464, 200 Constitution Avenue NW., Washington, D.C. 20210. Telephone 202-523-6807.

SUPPLEMENTARY INFORMATION: Pursuant to a recommendation of the Administrative Conference of the United States, the Secretary of Labor waived his entitlement to the exemption from rulemaking requirements of the Administrative Procedure Act (5 U.S.C. 553) for matters relating to public property, loans, grants, benefits, or contracts. Before the regulation went into effect, most agencies under the Secretary of Labor had already informally adopted APA rulemaking procedures. Therefore, the regulation merely reaffirmed existing policy.

However, it has become advisable to revoke in part the waiver of the exemption in order to assure that information-gathering procedures like those used by BLS are not subject to APA rulemaking requirements. The U.S. Court of Appeals for the D.C. Circuit has

recently held that methodology developed by the Bureau of Labor Statistics to establish unemployment figures used for allotment of funds under Title VI of the Comprehensive Employment and Training Act are "rules" which must be promulgated pursuant to APA notice and comment procedures. *Batterton v. Marshall*, No. 78-1414 (Aug. 28, 1980). The Court of Appeals' decision makes clear, however, that such methodology would ordinarily be exempt from APA procedures as a matter relating to public benefits, under 5 U.S.C. 553(a)(2). Had the Department not waived the exemption, these BLS procedures would not be subject to APA informal rulemaking requirements.

The Department's position has been that information-gathering procedures are not rules within the meaning of the APA, but rather investigatory functions not subject to APA requirements. Had the Department anticipated that such procedures could be deemed "rules" subject to APA notice and comment requirements, it would not have waived its right to invoke the exemption for information gathering relating to "public property, loans, grants, benefits, or contracts." The Department's concern is for the Bureau of Labor Statistics. The Bureau's statutory role is to accumulate information on labor-related subjects for use of the Congress, other government agencies, and the public. The Bureau's information-gathering activities are statistical in nature and are conducted on the basis of scientific principles. To subject purely statistical decision making to procedures required for review of policy decisions under the Administrative Procedure Act might subject BLS methodology to nonstatistical policy influences. It is essential to avoid equating statistical and policy decisions.

The Secretary has therefore determined that it is necessary to amend the existing regulation and reclaim the right to invoke the 5 U.S.C. 553(a)(2) exemption insofar as it covers the Bureau's information-gathering procedures. The Department does not intend to invoke the exemption for any other matters "relating to public property, loans, grants, benefits, or contracts," but will continue its practice of using APA notice and comment procedures for any such matters other than data collection procedures.

The original waiver of the exemption was not promulgated pursuant to APA notice and comment procedures because it was a general statement of policy and a rule of agency procedure within the meaning of 5 U.S.C. 553(b)(A). (See 36 FR 12976 (July 10, 1971)). For the same