

JAN 20 1969

January 16, 1969

William E. McCormick, Chairman
The B. F. Goodrich Co.
500 S. Main Street
Akron, Ohio 44318

Dear Bill:

In response to your letter of January 14, I would be pleased to serve as Chairman of the ad hoc committee on good manufacturing practices for food manufacturing plants. I will telephone you, Dr. Knapp and Mr. Philpitt during the week of January 20 to discuss this matter.

Very truly yours,

Frank P. DiPrima
Attorney

FPD:ma

cc: M. M. Hoover
Dr. W. A. Knapp ✓
V. H. Knoop
R. H. Philpitt

ASI 00002321

JAN 16 1969

Food, Drug, and Cosmetic Chemicals

The B.F. Goodrich Co.
500 S. Main St.
Akron, Ohio 44318

1/14/69

Mr. Frank P. DiPrima
Merck & Co., Inc.
Rahway, New Jersey 07065

Dear Frank:

I am sure you are familiar with the revised FDA order that appeared in the December 20 Federal Register on good manufacturing practices for food manufacturing plants. You recall that MCA objected to certain positions of the proposed regulation when it first appeared but these objections have not apparently been accepted, inasmuch as the December 20 regulation still contains them. Considerable revision has been made, and in recent discussions between Morgan Hoover and myself, we have both arrived at the feeling that a small subcommittee should study in detail this proposed regulation and establish a position on it for MCA. It might well be that our position will be the same as it originally was and, if so, we will merely reiterate it; however, there might be some other comments that we should make.

I would appreciate, therefore, if you would serve as the Chairman of this group, and by copy of this letter I am asking Bill Knapp and Dick Philpitt to also serve with you. All of you are within the same geographical area and, hopefully, this will facilitate any conversations or personal contacts that you might feel desirable. We have until mid-February to file whatever comments we wish to make.

Very truly yours,

W.E. McGernick
Chairman

mj
cc: W.A. Knapp
R.H. Philpitt
V.H. Knoop
M.H. Hoover

ASI 00002322

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

PICKLE PRODUCTS

Standardization of Quantity of Contents Declaration in Terms of Volume

In section 2 of the Fair Packaging and Labeling Act (Public Law 89-755; 80 Stat. 1296), which sets forth the intent of Congress in enacting that legislation, it is stated that "Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons." Section 4 of that act sets forth specific requirements for declaring quantity of contents.

To implement such requirements, § 1.8b(a) of the regulations for the enforcement of said act prescribes that "Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity."

A situation in the pickle industry that fosters consumer confusion has come to the attention of the Commissioner of Food and Drugs. For sliced pickles and pickle relish, two methods are now being used to declare quantity of contents—by weight and by volume. (In the case of one or two pickles packed in transparent sealed plastic bags, however, a single method of declaration by count is being used.) For many years most packers of pickle products have declared the quantity of contents in terms of volume. The declaration in terms of volume provides the consumer with accurate information and facilitates value comparisons.

Therefore, the Commissioner on his own initiative proposes that the declaration of quantity of contents be made uniform in volumetric terms on such products.

Accordingly, pursuant to the provisions of the Fair Packaging and Labeling Act (secs. 4, 5(a), 6(a), 80 Stat. 1297-1300; 15 U.S.C. 1453-55) and the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371), and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that § 1.8b be amended by adding thereto a new paragraph, as follows:

§ 1.8b Food labeling; declaration of net quantity of contents; when exempt.

(r) The declaration of net quantity of contents on pickles and pickle products, including relishes but excluding one or two whole pickles in clear plastic bags, shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart,

pint, and fluid ounce subdivisions thereof.

Any interested person may, within 60 days from the date of publication of this notice in the *Federal Register*, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: January 2, 1969.

J. K. KIRK,
Associate Commissioner
for Compliance.

[F.R. Doc. 69-332; Filed, Jan. 9, 1969;
8:48 a.m.]

[21 CFR Part 128]

HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

Extension of Time for Filing Comments

The proposal to promulgate Part 128—*Human foods; current good manufacturing practice (sanitation) in manufacture, processing, packing, or holding*, published in the *Federal Register* of December 20, 1968 (33 F.R. 19023), provided for the filing of comments thereon within 30 days of its publication date.

The Commissioner of Food and Drugs has received a request for an extension of such time and, good reason therefor appearing, the time for filing comments regarding proposed Part 128 is extended to February 18, 1969.

This action is taken pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: December 30, 1968.

J. K. KIRK,
Associate Commissioner
for Compliance.

[F.R. Doc. 69-333; Filed, Jan. 9, 1969;
8:48 a.m.]

Public Health Service

[42 CFR Part 81]

AIR QUALITY CONTROL REGIONS

Notice of Proposed Designation of Metropolitan Cincinnati Interstate Air Quality Control Region; Consultation With Appropriate State and Local Authorities

Pursuant to authority delegated by the Secretary and redelegated to the Commissioner of the National Air Pollution Control Administration (33 F.R. 9909), notice is hereby given of a proposal to designate the Metropolitan Cincinnati

Interstate Air Quality Control Region as set forth in the following new § 81.20 which would be added to Part 81 of Title 42, Code of Federal Regulations. It is proposed to make such designation effective upon republication.

Interested persons may submit written data, views, or arguments in triplicate to the Office of the Commissioner, National Air Pollution Control Administration, Ballston Center Tower II, Room 905, 801 North Randolph Street, Arlington, Va. 22203. All relevant material received not later than 30 days after the publication of this notice will be considered.

Interested authorities of the States of Ohio, Kentucky, and Indiana, and appropriate local authorities, both within and without the proposed region, who are affected by or interested in the proposed designation, are hereby given notice of an opportunity to consult with representatives of the Secretary concerning such designation. Such consultation will take place at the Federal Office Building, Room 8016, 550 Main Street, Cincinnati, Ohio 45202, beginning at 10 a.m., January 27, 1969.

Mr. Doyle J. Borchers is hereby designated as Chairman for the consultation. The Chairman shall fix the time, date, and place of later sessions and may convene, reconvene, recess, and adjourn the sessions as he deems appropriate to expedite the proceedings. State and local authorities wishing to participate in the consultation should notify the Office of the Commissioner, National Air Pollution Control Administration, Ballston Center Tower II, Room 905, 801 North Randolph Street, Arlington, Va. 22203, of such intention by January 20, 1969.

A report prepared for the consultation, entitled "Report for Consultation on the Metropolitan Cincinnati Interstate Air Quality Control Region," is available upon request to the Office of the Commissioner.

In Part 81 a new § 81.20 is proposed to be added to read as follows:

§ 81.20 Metropolitan Cincinnati Interstate Air Quality Control Region.

The Metropolitan Cincinnati Interstate Air Quality Control Region consists of the territorial area encompassed by the boundaries of the following jurisdictions (including the territorial area of all municipalities (as defined in section 302(f) of the Clean Air Act, 42 U.S.C. 1857(f)) geographically located within the outermost boundaries of the area so delimited):

In the State of Ohio:
Clermont County.
Hamilton County.
In the Commonwealth of Kentucky:
Boone County.
Cambell County.
Kenton County.
In the State of Indiana:
Dearborn County.

This action is proposed under the authority of sections 107(a) and 301(a) of the Clean Air Act, section 2, Public

in nature may be published at any time without prior notice.

(d) The Department may, at any time after receiving a recommended revision or a recommended amendment from a Standing Committee, and prior to publication, make editorial or other minor changes which are deemed necessary to reduce ambiguity or improve clarity within the standard; *Provided, however*, That no substantive changes shall be made in the standard.

§ 10.11 Withdrawal of a published standard.

(a) Any standard published under these or any previous procedures may be withdrawn by the Department at any time. Such action will be taken, if, after consultation with the Standing Committee, as provided in paragraph (b) of this section, and after public notice, the Department determines that the standard is obsolete, technically inadequate, no longer generally acceptable to and used by the industry, inconsistent with law or established public policy, not in the public interest, or otherwise inappropriate, and revision or amendment is not feasible or would serve no useful purpose.

(b) Before withdrawing a published standard the Department will review the relative advantages and disadvantages of amendment, revision, development of a new standard, or withdrawal, with the members of the Standing Committee for that standard, if such committee was appointed within the previous 5 years.

(c) Public notice of intent to withdraw an existing standard will be given and a 30-day period will be provided for the filing of written objections to the withdrawal. Such objections to the withdrawal will be considered and analyzed by the Department before a final decision is made to withdraw the standard. The Department will give public notice of the withdrawal of an existing standard not less than 60 days prior to the effective date of such withdrawal.

(d) Withdrawal will terminate the authority to refer to the published standard as a voluntary standard developed under Department of Commerce procedures, from the effective date of the withdrawal.

§ 10.12 Effect of procedures.

These procedures supersede all commodity standards procedures previously issued by the Department of Commerce or any of its offices or bureaus, but current commodity standards published under any such superseded procedures will remain in effect as Voluntary Product Standards. Nothing contained in these procedures shall be deemed to apply to the development, publication, revision, amendment, or withdrawal of any standard which is not identified as a "Voluntary Product Standard" by the Department. The authority of the Department with respect to engineering standards activities generally, including the authority to publish appropriate recommendations not identified as "Volun-

tary Product Standards," is not limited in any way by these procedures.

Dated: December 17, 1968.

JOHN P. KIRKMAN,
Assistant Secretary
for Science and Technology.

(P.R. Doc. 10-10101; Filed, Dec. 19, 1968;
8:47 a.m.)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 128]

HUMAN FOODS

Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing, or Holding

In the FEDERAL REGISTER of December 15, 1967 (32 F.R. 17980), the Commissioner of Food and Drugs proposed the promulgation of Part 128 covering current good manufacturing practice (sanitation) in the manufacture, processing, packing, or holding of human foods. Comments were received in response thereto which have resulted in significant changes in the proposed regulations, and the Commissioner concludes that a revised proposal should be published as set forth below.

These regulations would establish criteria for good manufacturing practices for effective sanitation control in the manufacture, processing, packing, or holding of human foods to effect compliance with section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. They set forth standards of sanitary food processing that would result in a clean and wholesome end product. Some of these standards are expressed in mandatory terms; others are directory. All should be observed to satisfy the requirements of current good sanitation practice in food processing and holding.

While these regulations would establish general criteria for the human food industry, they would not apply to those establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the Act, which are ordinarily cleaned, prepared, treated, and/or otherwise processed before being marketed to the consuming public. The Commissioner believes that if necessary special regulations should be developed for operations in this category.

Any interested person not within the exception for raw agricultural commodities, who believes circumstances warrant an exception and special regulations for his operation, may submit a request for exception together with a written justification in support of the request addressed to the Commissioner, Food and Drug Administration, 200 C Street SW.,

Washington, D.C. 20204. Additional specific regulations establishing criteria for particular segments of the food industry will be the subject of regulations to these general regulations.

Therefore, pursuant to the provisions of the Act (secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)), and under authority delegated to him (21 CFR 2.130), the Commissioner proposes that a new Part 128 be added to Title 21, Chapter I, as follows:

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

Sec.

128.1 Definitions.

128.2 Current good manufacturing practice (sanitation).

128.3 Plant and grounds.

128.4 Equipment and utensils.

128.5 Sanitary facilities and controls.

128.6 Sanitary operations.

128.7 Processes and controls.

128.8 Personnel.

AUTHORITY: The provisions of this Part 128 issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a).

§ 128.1 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Readily cleanable" means accessible and of such design, material, and finish that residues from or caused by processing operations may be removed by normal in-place or disassembly cleaning methods.

(c) "Plant" means the building or buildings, or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(d) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other micro-organisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

§ 128.2 Current good manufacturing practice (sanitation).

The criteria in §§ 128.3 through 128.8 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption has been prepared, packed, and held under sanitary conditions.