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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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MAR 21 1974

The Honorable Frank E. Moss
Chairman, Subcommittee for Consumers
Committee on Commerce
United States Senate

Dear Mr. Chairman:

Your letter of July 12, 1973, requested that we review activities which led to the issuance by the Food and Drug Administration (FDA) of Compliance Policy Guide No. 7210.2, dated July 8, 1969, which changed FDA policy and permitted the use of the term "potato chips" for products made from dried or dehydrated potatoes. You also requested that we evaluate whether FDA made this change in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the customary procedures of FDA.

We have concluded that FDA issued Compliance Policy Guide (CPG) No. 7210.2 in accordance with its customary procedures. However, with regard to whether FDA made the change in accordance with the FD&C Act, the statutory authority to render a decision on actions by FDA under the FD&C Act has been placed in the Federal courts and there have been no suits against FDA to provide a test of its action in issuing CPG No. 7210.2.

From FDA's inception, companies have sought its opinion, before marketing products, on whether products or labeling would trigger regulatory action by FDA. To preclude any loss of competitive advantage, FDA in its deliberations on these requests, has made a practice of meeting only with the company requesting its advice. However, after opinions were delivered and when they were of general interest, FDA published them as "Trade Correspondence." Also, FDA advised its field offices of these opinions to guide them and to promote consistency in their compliance activities.

FDA began issuing CPG's on June 20, 1969, to guide its personnel in arriving at compliance decisions regarding the provisions of the FD&C Act and other acts on which FDA has established an enforcement position. The CPG's contained the advisory opinions formerly published as "Trade Correspondence," and compliance policies derived from other sources.

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An FDA official advised us that no restructured foods appeared on the market prior to "potato chips" made from dehydrated potatoes and other ingredients. Therefore, FDA had no established opinion regarding restructured foods.

In 1964, the first "potato chips" made from dehydrated potatoes, "Chipnics Homogenized Potato Chips," were marketed by the Sealtest Division of the National Dairy Products Corporation. In September 1967, General Mills, Inc. (GMI), began marketing "Chipos," "potato chips" made from dehydrated potatoes and rice flour. During September 1968, the Proctor & Gamble Company (P&G) began marketing "Pringle's Newfangled Potato Chips," (Pringle's) made from dehydrated potatoes.

Each of the manufacturers of these new potato products was told by FDA that the use of the term "potato chips" was not an accurate description of their product. All three responded by either letter or conference to FDA's notification, with perhaps the most significant response being provided by P&G when its representatives met with FDA personnel on November 25, 1968.

The P&G representatives contended that Pringle's, though processed differently, were nutritionally the same as potato chips made from thin slices of raw potatoes, and for this reason, should not require further distinction on the label. P&G also presented marketing research reports indicating consumer acceptance of Pringle's as potato chips.

In internal memorandums dated December 5, 1968, and January 10, 1969, FDA officials concluded that the composition, appearance, and organoleptic characteristics of Pringle's were similar to those of the traditional potato chips and, therefore, it could not deny P&G the use of the term "potato chips" for its product.

On January 15, 1969, in a letter to P&G, the Director, Division of Case Guidance, FDA, concluded that the name "potato chips" did apply to Pringle's. However, he stipulated that the consumer's attention should be clearly called to the fact that the product is made from dehydrated potatoes. Because FDA's letter to P&G contained a newly established position of general interest, FDA issued CPG No. 7210.2 stating the agency's official position regarding the labeling of restructured potato chips.

Your letter referred to correspondence from Mr. Delbert W. Hadfield of the Clover Club Foods Company in which he expressed the opinion that the Federal courts relied on FDA's CPG No. 7210.2 in arriving at its

decision in a suit by the Potato Chip Institute, International, against GMI. In 1971 the Potato Chip Institute, International, and the Weaver Potato Chip Co., Inc., brought a suit seeking to enjoin GMI from advertising or otherwise promoting Chipos, which was made from dehydrated potatoes rather than raw potatoes, by use of the words "potato chips." At that time GMI was no longer including rice flour as an ingredient of Chipos.

The District Court denied the request, but issued an injunction preventing GMI from advertising Chipos employing the words "potato chips" without an accompanying prominent declaration that the product was made from dried or dehydrated potatoes. Potato Chip Institute V. General Mills, Inc., 333 F. Supp. 173 (D. Nebraska 1971).

The decision was appealed by the Potato Chip Institute, but the appellate court affirmed the ruling of the District Court. The appellate court stated that its reasons for upholding the ruling of the District Court rendered immaterial the extent, if any, to which the District Court relied upon FDA's CPG No. 7210.2. Potato Chip Institute V. General Mills, Inc., 461 F. 2d 1088 (8th Cir 1972).

Since receiving your letter of July 12, 1973, there have been further developments in this matter. In the Federal Register of August 2, 1973, FDA proposed a regulation under 21 CFR 102 which would establish common or usual names for five restructured foods, including "potato chips" made from dehydrated potatoes. Any question as to the validity of FDA's final regulation concerning "potato chips" made from dehydrated potatoes may be pursued through the Federal courts by any person adversely affected.

In this regard, P&G and other interested parties have questioned the validity of 21 CFR 102. The procedure contained in 21 CFR 102 for establishing common or usual names for nonstandardized foods was first established by FDA on March 14, 1973 (38 F.R. 6964 et. seq.). In establishing the procedure, FDA cited its authority under, among others, section 701(a) of the FD&C Act which states:

> "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary."

Several parties objected to 21 CFR 102, arguing that it

> "* * * is contrary to congressional intentions that the common or usual name shall be established only under section 401 with safeguards of section 701(e) of the act."

FDA's response to the objection was:

> "The Commissioner agrees that a name may be determined by regulation through the establishment of a standard of identity under section 401 of the act, and proposes to continue utilizing this alternative method whenever appropriate. Section 401 does not, however, preclude the establishment of a common or usual name under other sections of the act."

Another objection to 21 CFR 102 was that there was no need for new regulations to establish the common or usual names of foods because this could be done by establishing a definition and standard of identity for foods under section 401 of the act. The Commissioner, FDA, concluded that standards of identity are appropriate and useful and will continue to be promulgated when there is a need to prescribe the entire compositional requirements for a food in addition to the name of the food. The Commissioner stated, however, that often there is a need simply to establish a uniform and informative name for a food without prescribing the compositional aspects of a food under a standard and, in these instances, a standard of identity is inappropriate.

In response to several other objections by interested parties that there were no provisions in the proposal for formal hearings as required under section 701(e), the Commissioner noted that hearings are not required for regulations promulgated pursuant to section 701(a).

The new procedure promulgated under authority of section 701(a) does not provide the following safeguards prescribed in section 701(e):

--A right to a public hearing (with a correlative right of cross-examination of witnesses provided by FDA regulation 21 CFR 2.81(a)).

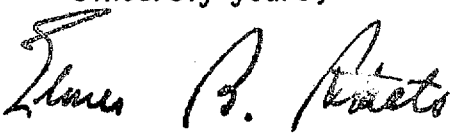
--An automatic stay of the effective date of provisions objected to until they can be reviewed.

In addition, we noted that the new procedure places judicial review in a Federal district court instead of a circuit court of appeals.

Whether the procedure for formulating these regulations setting common or usual names is statutorily permissible is a matter for the courts to determine.

We trust that this information will serve your needs and we will be pleased to meet with you if you should have any further questions.

Sincerely yours,



Comptroller General
of the United States