

DEPARTMENT OF HEALTH EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D. C. 20204

October 28, 1968

Dr. Howard C. Spencer
Biochemical Research Laboratory
Building 1803
The Dow Chemical Company
Midland, Michigan 48640

Re: Food Additive Master File 100

Dear Dr. Spencer:

This refers to your conference on July 30, 1968, with our Bureau of Science personnel concerning the establishment of a "Quality Standard" to permit the presence of small amounts of radioactivity unintentionally added to steam used in the processing of products subject to the Federal Food, Drug, and Cosmetic Act. We acknowledge also receipt of the various written materials and letters provided on this subject.

We have designated the information provided as Food Additive Master File 100. Additional material and correspondence should bear this number for ease of reference.

The basic issue appears to be whether or not FDA can establish a regulation permitting the unintentional addition of radionuclides to process steam, the use of which may add minute amounts of the radioactive materials to foods, drugs, and cosmetics produced with the contaminated steam.

Recognizing that there are certain differences in the law as it covers these different products, we think that we cannot authorize the deliberate addition of carcinogenic materials to any of them. Certainly in the case of food additives, the law itself proscribes the issuance of any regulation as requested, because radionuclides are recognized as being carcinogenic. We think that the addition of such material to drugs and cosmetics is also undesirable.

Dr. Beamer's letter of August 26, 1968, gives some information on the frequency of leaks in existing steam generating reactors. However, it is still not clear that it is uneconomic to repair the facility as soon as a suitably sensitive detecting instrument registers radioactivity in the process steam circuit. Certainly any food or drug

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manufacturing plant ordinarily shuts down to correct any situation that leads, or may lead, to contamination of the product. We can find no basis for a conclusion that in this case some health risk should be accepted with known carcinogenic materials.

Sincerely yours,

J. K. Kirk
Associate Commissioner
for Compliance