)(1) The Commissioner, on his own
tiative or on the petition of any in-
ested person, pursuant to part 10 of
s chapter, may issue a notice in the
)ERAL REGISTER proposing to deter-
ıe that a substance is not GRAS and
food additive subject to section 409
:he act. Any petition shall include
relevant data and information of
type described in §571.130(b) of this
pter. The Commissioner will place
of the data and information on
ch he relies on public file in the Di-
on of Dockets Management and will
ude in the FEDERAL REGISTER no-
the name of the substance, its
wn uses, and a summary of the
s for the determination.
) The FEDERAL REGISTER notice will
w a period of 60 days during which
interested person may review the
ı and information and/or file com-
ıts with the Division of Dockets
ıagement. Copies of all comments
l be made available for examina-
in the Division of Dockets Man-
nent.
) The Commissioner will evaluate
:omments received. If he concludes
there is a lack of convincing evi-
:e that the substance is GRAS or is
:rwise exempt from the definition
food additive in section 201(s) of
ıct, he will publish a notice thereof
he FEDERAL REGISTER. If he con-
es that there is convincing evi-
e that the substance is GRAS, he
publish an order in the FEDERAL
STER listing the substance in this
hapter E as GRAS.
A FEDERAL REGISTER notice deter-
ng that a substance is a food addi-
shall provide for the use of the ad-
e in food or food-contact surfaces
llows:
It may promulgate a food additive
lation governing use of the addi-

It may promulgate an interim
additive regulation governing use
e additive.
It may require discontinuation of
se of the additive.
It may adopt any combination of
above three approaches for dif-
t uses or levels of use of the addi-

If the Commissioner of Food and
s is aware of any prior sanction

for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under this subchapter E. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this subchapter E., incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 14, 1977; 54 FR 18281, Apr. 28, 1989]

PART 571—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.

Subpart B—Administrative Actions on Applications

AUTHORITY: 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

SOURCE: 41 FR 38647, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§571.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food-additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner _____
Post office address _____
Date _____
Name of food additive and proposed use _____

Food and Drug Administration
CENTER FOR VETERINARY MEDICINE,
Director, Division of Animal Feeds (HFV–220), 7500 Standish Pl., Rockville, MD 20855.

DEAR SIRS: The undersigned, _____

submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and

Cosmetic Act with respect to _____

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the

food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to ensure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.

If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

(A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.)

F. Proposed tolerances for the food additive, if tolerances are required in order to ensure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

Yours very truly,

Petitioner _____

By _____

(Indicate authority)