DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: November 4, 2009

From: Daniel E. Folmer, Ph.D.; FDA liaison to the United States Pharmacopeia's Food Ingredients Expert Committee

Subject: Resubmission of FDA comments to the June 2009 Food Chemicals Codex Forum originally sent by e-mail on September, 28 2009.

To: Ms. Kristie Bowman, USP Senior Scientific Associate

FDA originally submitted comments to the June 2009 Food Chemicals Codex Forum on 9/28/2009 by means of e-mail. At the request of the United States Pharmacopeia (USP), we are resubmitting the comments on FDA letterhead.

(Original FDA comment from 9/28/2009 e-mail from D. Folmer (FDA) to K. Bowman (USP)).

We would like to comment on the proposed Food Chemicals Codex (FCC) monographs for lutein and tagetes extract. Our comments are separated, below, by monograph.

Lutein

The draft FCC monograph for lutein states that lutein has the functions of a source of lutein and of a color. While we understand that the FCC is an international compendium, we wish to note that lutein is not currently permitted for use in the United States (U.S.) as a color additive in food. While there are several successful generally recognized as safe (GRAS) notices for the use of lutein as an ingredient in food, there are currently no regulations permitting the use of lutein as a color additive in the U.S. The Food and Drug Administration (FDA) stated in its responses to the successful GRAS notifications that if the use of lutein results in color being imparted to the food, premarket review and approval of lutein as a color additive may also be necessary. Unlike the food additive definition in Section 201(s) of the Federal Food, Drug and Cosmetic Act, there is no GRAS exemption for color additives. Thus, substances that are GRAS for food additive uses still require premarket approval before they can be used as color additives in food products sold in the U.S.

Tagetes Extract

"Tagetes (Aztec marigold) meal and extract" is currently regulated for use in the U.S. under 21 CFR 73.295 as a color additive exempt from certification for use in chicken feed only. It is not authorized for use as a color additive in human food. As outlined in Table 1, below, there are several specifications in §73.295(b)(2) that are required for use in the U.S., but are not present in the draft FCC monograph for Tagetes extract.

Table 1. Specifications found in 21 CFR 73.295 that are not present in the draft FCC monograph for Tagetes extract.

Specification	Value1
Melting point	53.5-55.0°C
Iodine value	132-145
Saponification value	175-200
Acid value	0.60-1.20
Titer	33.5°-37.0 °C
Unsaponifiable matter	23.0 percent-27.0 percent

In addition, §73.295(b)(2) requires a hexane residue value2 of not more than (nmt) 25 ppm (mg/kg), which is lower than the acceptance criteria for residual solvent in the draft FCC monograph of nmt 50 mg/kg hexane.

We ask that you take into consideration the specifications found in §73.295 when finalizing the monograph for Tagetes extract.

Thank you for the opportunity to comment on these monographs.

Best regards,

Daniel E. Folmer

Daniel E. Folmer, Ph.D.
FDA Liaison to the Food Ingredient Expert Committee

1 All determinations are made on the initial extract of the flower petals (after drying in a vacuum oven at 60° C for 24 hours) prior to the addition of oils or ethoxyquin.
2 The hexane determination is made on the color additive after the addition of oils and ethoxyquin.