



CK Life Sciences Limited
長江生命科技有限公司

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852
Attn: Yuan Yuan Chiu

Dear Sir,

Hereby we would like to make a supplementary comment on the Guidance for Industry – Botanical Drug Products drafted by US Department of Health and Human Services, FDA in Aug 2000, as attached. We realize that it is probably too late to submit comments to the draft, but we still would like to request for your serious consideration.

Please do not hesitate to contact me at (852) 2126 1291 or barbara.chan@ck-lifesciences.com if you have any questions regarding the comments.

With my best regards

Yours sincerely

Barbara Chan Ph.D.

Project Manager

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Comments:

Regarding the 2nd paragraph on page2 "... botanicals included plant materials, algae, **macroscopic fungi**, and It does not include fermentation products such as **products fermented with yeasts**, bacteria, and other **microscopic organisms**,because these substances can readily be fully characterized”:

It is well appreciated that the reason not to include fermented products of microscopic organisms is because these products such as proteins, enzymes and polysaccharides, are easily characterized. However, the use of the microscopic fungi themselves has not been mentioned at all. For example, β 1,3-glucans and many derivatives are potent immunomodulators (Sherwood ER et al 2001, Vetvicka V et al 2002). They can be identified from various botanical sources include but not limit to macroscopic fungi (e.g. mushroom) and microscopic fungi (e.g. bakers' yeasts) (Vetvicka V et al 2002). As a result, the use of microscopic fungi such as yeasts should be included in the same manner as that of macroscopic fungi such as mushrooms. We suggest deleting the word “macroscopic” from the phrase “macroscopic fungi”.

Reference:

1. Sherwood ER, Varma TK, Fram RY, Lin CY, Koutrouvelis AP, Toliver-Kinsky TE. (2001) Glucan phosphate potentiates endotoxin-induced interferon-gamma expression in immunocompetent mice, but attenuates induction of endotoxin tolerance. Clin Sci (Lond);101(6):541-50.
2. Vetvicka V, Tarayama K, Mandeville R, Brousseau P, Kournikakis B, Ostroff G. (2002) Pilot study: Orally administered yeast 1,3-glucan prophylactically protects against anthrax infection and cancer in mice. JANA 5(2):1-5.