

2111 '01 APR 26 P1:51

April 24, 2001

Dockets Management Branch
Food and Drug Administration
HFA-305
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Dietary Supplement Industries' Proposed
GMP's Objection to "Exclusions"
Provision Docket No. 96N-0417

Dear Sir:

The Dietary Supplement Industries' proposed GMP Docket No. 96N-0417 contains a gigantic loophole which will in effect, negate many of the under critical GMP's for "Production and Process Controls" involving raw materials. Specifically, the proposed GMP's in this section, a manufacturer can avoid responsibility for raw material inspection and safety by receiving a "guarantee or certification of examination" from the supplier, i.e., the "In lieu of Provision".

However, the same Proposed Industry GMP's contains an "Exclusion" provision which would make any such supplier exempt from the GMP's. As stated in the Proposed GMP section "Exclusion":

"Exclusions

The following operations are not subject to this part:
Establishments engaged solely in the harvesting, storage, or distribution of
one or more 'raw agricultural commodities,' as defined in section 201(r) of
the act, which are ordinarily cleaned, prepared, treated or otherwise
processed before being marketed to the consuming public."

In short, what good is GMP's that allows a manufacturer to accept an "In lieu of certificate" from suppliers of the ingredients used in dietary supplements are exempt? As I am sure the FDA has seen in the past, such "certificates and guarantees" provide little, if any assurance, that the herbs and other ingredients, which include animal parts, are properly tested and examined for safety, adulteration, or contamination.

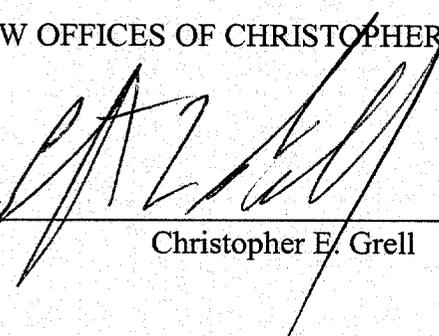
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In short, the "Exclusion" language and the "certificate or guarantee" in lieu of provision should be stricken from the Proposed GMP's so that the public is assured that the ingredients used in dietary supplements are covered by these GMP's.

Thank you.

Very truly yours,

LAW OFFICES OF CHRISTOPHER E. GRELL

By: 

Christopher E. Grell

CEG:jw

cc: Washington Post
New York Times
San Francisco Chronicle
Dietary Supplement Safety Committee