[illegible] AUG 11 [illegible]

Docket No. 96N-0417

Before
The United States of America
Department of Health and Human Services
Food and Drug Administration

Pacific Botanicals, LLC

Comments on
the Proposed Rule for
Current Good Manufacturing Practice
in Manufacturing, Packing, or Holding
Dietary Ingredients and Dietary Supplements

Pacific Botanicals, LLC
4840 Fish Hatchery Rd.
Grants Pass, Oregon 97527
541-479-7777
pacbot@internetcds.com

96N-0417

C 170

1507 '03 AUG 11

6 August 2003
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Pacific Botanicals LLC, a bulk botanical, single ingredient grower and supplier submits the following comments in response to the FDA's proposed rule for current good manufacturing practices.

Subpart A- General Provisions, 111.6 Exclusions

We strongly recommend that the farm exclusion be expanded to include some other typical preliminary farm processes as follows:

> *The regulations in this part do not aply to a person engaged soley in activities related to the harvesting, cleaning, drying, storage and other basic farm operations such as cutting, sifting and grinding.*

Pacific Botanicals LLC. is not a manufacturer and only handles and sells single botanical ingredients. We are a bulk material supplier and have systems in place for quality assurance such as: Good Agricultural Practices. Dryer logs, lot numbers, high end inventory management software for product traceability and loss tracking. Production logs for all milling operations. Equipment logs and pest control logs, to name a few.

Pacific Botanicals feels that the main responsibility of proving product identity, purity, quality, strength and composition should be that of the finished product marketer and manufacturer due to serious cost considerations for the small agricultural producer.

Marketers and Manufacturers of finished dietary supplements should be required to prove that the ingredients they procure and the products they market are safe and authentic.

<u>Subpart E-</u> Production and Process Controls 111.35(K)

In regard to *"ensuring that there are no toxic compounds present that may adulterate"*

This is a wide reaching statement. If there is no farm exemption for this in the final rule there should be set maximum allowable limits for these toxins of primary concern. Ochratoxin and mycotoxins are often found in the U.S. food supply and maximum allowable levels for these should not be less than is allowable for food.

If the published rule for cGMP's states a maximum allowable level for undesirable microorganisms, it should be more in step with recent industry work with the American Herbal Products Association as the referenced USP limits are not realistic for raw botanical ingredients. This is especially true in organic production systems of which we are a part. Many of us have been proactive in defining realistic microbiological level limits and feel our experience should be reflected in the final rule.

Subpart E- Production and Process Controls 111.35(G)

In regard to the statement on page 12198: *using a suppliers certificate of analysis document in lieu of performing testing on each shipment lot is not appropriate"*

We feel there should be an exception to this rule if a supplier's testing has been validated through audits at appropriate intervals.

Subpart E- Production and Process Controls 111.35(e)(1)

Product specification sheets could be modeled after pharmacopoeia monographs other than those listed in the proposed rule. There are other official and non-official yet authoritative information sources that should be acceptable and referenced in the rule such as: American Herbal Pharmacopoeia, The World Health Organization and the European Pharmacopoeia to name just a few. The AHP Monographs have been recognized by the primary trade organizations as authoritative and scientifically valid and should be recognized by the FDA as such.

Subpart F- Holding and distributing

Regarding the salvage of returned material. We believe that if there is sufficient evidence that a botanical ingredient was stored in it's original container, was unopened and/ or was returned due to a customer error, that the material should not have to undergo expensive testing to be salvaged. We are a small producer supplying small material lots and this would be very cost prohibitive and result in the unecessary disposal of costly product.

VII. Analysis of Economic Impacts

The economic impacts of the proposed GMP's would be hugely significant to small producers like ourselves. The marketplace for botanical ingredient suppliers is very volatile and competitive. We believe this would have severe impact on us and many businesses that we know of and conduct business with.