DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 24, 2013

Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, Suite 918
Silver Spring, MD 20910

Dear Mr. McGuffin:

Your petition to the Food and Drug Administration requesting the Agency to formally rescind FDA's policy of prohibiting Agency investigators from quoting or citing the cGMP regulations upon which they base their inspectional observations within 483s issued to conventional food and dietary supplement facilities; and revise the IOM to expressly require that 483s issued to conventional food and dietary supplement facilities reference each cGMP regulation to which the Agency investigator's listed observations relate, was received by this office on 10/18/2013. It was assigned docket number FDA-2013-P-1291/CP1, and it was filed on 10/24/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)