Hersil s.a.
LABORATORIOS

March 24, 2003

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Messrs.
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sirs:

I work for a laboratory with more than 37 years of experience in the manufacturing, distribution and commercialization of pharmaceutical and natural products in Lima, Peru.

My customers and I appreciate the significance of the Dietary Supplement Health and Education Act of 1994 with regard to protecting our right to choose how we care for ourselves.

I am concerned that FDA has only just begun to implement key sections of DSHEA. For instance, the agency recently released its proposed good manufacturing practices for the industry, and yet is immediately calling for suggestions for increased legislative authority in order to better regulate the supplement industry. Shouldn't you first give DSHEA a chance to work as it was intended to before calling for new laws?

Please also don't overlook that DSHEA actually increased FDA's enforcement powers. FDA can seize a dietary supplement if it presents an unreasonable or significant risk of illness or injury. In addition, the government can stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard. In sum, I agree with the former FDA commissioner, Dr. Jane Henney, that DSHEA provides FDA with the necessary legal authority to protect public health.

DSHEA improved consumer access to dietary supplements and information about them, while increasing consumer protection against unsafe products and false and misleading claims. I strongly support DSHEA and do not think any additional legislative authority is necessary for FDA to regulate ephedra or any other dietary supplement.

Sincerely,

MARK SILVA DELLAHA
Director Manager

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