



Center for Regulatory Effectiveness

Suite 700
11 Dupont Circle, N.W.
Washington, D.C. 20036-1231
Tel: (202) 265-2383 Fax: (202) 939-6969
www.TheCRE.com

0944 '06 JUN -6 AM:31

June 6, 2006

Andrew C. Von Eschenbach
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20582

RE: REQUEST FOR PUBLIC COMMENT AND PUBLIC MEETING ON PETITION REQUESTING FDA AMEND ITS REGULATIONS FOR PRODCUTS COMPOSED OF ENGINEERED NANOPARTICLES GENERALLY AND SUNSCREEN DRUG PRODUCTS COMPOSED OF ENGINEERED NANOPARTICLES SPECIFICALLY (FDA Docket No. 2006P-0210, filed May 17, 2006)

By Email and Messenger

Dear Mr. Von Eschenbach:

On behalf of the Center for Regulatory Effectiveness, I ask that the FDA allow public comment and hold a public meeting on the above-captioned Petition.

Several NGOs filed the Petition. They request that the FDA implement the NGO's preferred scheme for regulating products composed of engineered nanoparticles. The Petition specifies the NGO scheme in considerable detail.

Nanotechnology is a promising and fast emerging method of manufacture both domestically and abroad. Neither the FDA nor any other federal agency has developed a comprehensive scheme for regulating nanotechnology. Both the FDA and other agencies (e.g., EPA and NIOSH) are

2006P-0210

C1

Center for Regulatory Effectiveness

working on such a scheme. We believe the same is true of foreign regulatory bodies. Several international standard-setting organizations are also working on issues critical to any government regulation of nanotechnology.

The FDA's action on the Petition will have far reaching and precedent setting impact in both the United States and foreign countries. The FDA's action will affect stakeholders all over the world on all sides of the issue.

Consequently, the CRE requests that the FDA allow public comment and hold a public meeting on the Petition before acting on it.

I will not set forth at this point CRE's views of how the Petition should be decided and how the FDA should address nanotechnology. I will, however, suggest a framework for public comment and public meeting on the Petition.

First, the FDA should request that the public comment on the regulatory scheme advocated by the Petition. If commenters disagree all or in part with this scheme, then they should be asked to provide specific alternatives. The FDA should not continue to decide nanotech issues on a case-by-case basis. The Agency should instead develop a rational, principled and consistent framework for deciding these issues.

Second, the FDA should emphasize in its Federal Register notice of public comment and meeting that the Agency's decision on the Petition, and the Agency's regulation of all nanoengineered products, must comply with the requirements of the Information Quality Act and with the FDA's guidelines implementing the IQA. For example, the FDA's IQA Guidelines specifically apply to FDA's response to the Petition.¹

Third, given the importance and impact of this issue, the FDA should announce that the Petition, and all specific nanoengineered products being reviewed by the FDA, will be placed on the FDA regulatory calendar well in advance of any Agency action on the Petition or on the specific products. This step should provide the interested public sufficient time and opportunity to comment on those actions.

Fourth, the FDA should seek comment on the Petition by all other parts of the federal government dealing with nanotechnology. The FDA should also seek comment by the states and by international standard-setting organizations. The National Technology Transfer Advancement Act of 1995 requires that EPA consult with these standard-setting organizations during FDA's regulation of nanotech. The Tech Transfer Act also requires that EPA use the nanotech standards developed by these standard-setting bodies unless to do so would be inconsistent with applicable

¹ FDA IQA Guidelines at Section III.f., available online at <http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml>

Center for Regulatory Effectiveness

of nanoengineered products raises many inter-disciplinary concerns and requires inter-disciplinary expertise.

In conclusion, the Petition has placed the FDA in the vanguard of nanotech regulatory issues. We understand that the FDA is already planning on a general public meeting on nanotechnology in October 2006.³ We suggest that the Petition and the concerns addressed in our letter be part of that general meeting.

Respectfully submitted,


Jim J. Tozzi
Member, CRE Board of Advisors

CC:

Docket No. 2006P-0210
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

³ 71 FR 19524 (April 14, 2006).