

Welcome

00N-0598

TS3

# Today's Meeting

- Implementation of *Pearson v. Shalala*
- Claims About Mitigation or Treatment of an Existing Disease

## *Pearson v. Shalala*: Recent Chronology

District Court Rules in Favor of Government: 01/98

Court of Appeals Reverses District Court's Decision  
and Rules in Favor of Pearson: 01/99

Court of Appeals Denies Government's Petition for  
Rehearing: 04/99

## ***Pearson v. Shalala*: U.S. Court of Appeals Decision**

- FDA Must Reconsider Whether to Authorize the Four Health Claims
- In absence of “Significant Scientific Agreement” (SSA), FDA Must Determine if the Scientific Evidence in Support of the Four Health Claims Outweighs the Scientific Evidence Against the Claims
- If So, FDA Must Consider Whether a Disclaimer or Other Qualifying Language Could Make the Health Claim Non-Misleading to Consumers
- FDA Must Clarify the SSA Standard for Authorizing Health Claims

## **FDA Implementation of the *Pearson* Decision**

1. July, 1999: Added as a High Priority (“A” List) to 1999 CFSAN Program Priorities.
2. August, 1999: Issued Contract for a Literature Review for the Four Health Claims.
3. September, 1999: Published FR Notice Soliciting Scientific Data on the Four Health Claims.
4. December 1, 1999: Published FR Notice on Strategy to Implement Court’s Decision.

## **December 1999 Strategy to Implement *Pearson* Decision**

- Update Scientific Evidence on the Four Claims.
- Issue Guidance Clarifying the “Significant Scientific Agreement” Standard.
- Hold a Public Meeting to Solicit Input on Changes to General Health Claim Regulations for Dietary Supplements in Light of *Pearson* Decision.
- Conduct a Rulemaking to Reconsider the General Health Claims Regulations for Dietary Supplements in Light of the *Pearson* Decision.
- Conduct Rulemakings on the Four *Pearson* Health Claims.

## FDA Implementation - continued

5. December, 1999: Issued Guidance for Industry on Significant Scientific Agreement in the Review of Health Claims.
6. January, 2000: Extended Comment Period on FR Notice as Requested by Plaintiffs, until April 3, 2000.
7. January, 2000: Included Implementation of *Pearson* Decision as a High Priority in the “Dietary Supplement Strategic Plan” and “2000 CFSAN Program Priorities.”
8. April, 2000: Convened a Public Meeting to Solicit Input on Changes to General Health Claim Regulations for Dietary Supplements in Light of *Pearson* Decision.

## **What We Want To Accomplish Today**

1. Should health claims be allowed on dietary supplements on a basis other than significant scientific agreement? If so, what should that basis be and what are appropriate criteria for making decisions about allowing such claims?
2. If such health claims on dietary supplements are to be appropriately qualified so that consumers are not misled, what should be the characteristics of such qualifying language? Should FDA require any other information to assist consumers in evaluating health claims and prevent them from being misled?

3. Should health claims go beyond claims about reducing the risk of a disease to include claims about mitigation or treatment of an existing disease, or are such claims drug claims? Where is the boundary, if any, between these claims?

# **Process for Today's Meeting**

- Panels
- Speakers
- Written Comments
- Transcript