

FDA/MA

Codified Good Guidance Practice
and makes it clear that guidances
do not establish "requirements"

Yet within the last month my company
in a meeting with FDA reviewers
was told they must plan two
adequate & well controlled trials which
would provide a safety data base
to meet the ICH E1 level
and duration of experience.

How do you plan to get the
flexibility message into the
review staffs day to day work?

① Temple
CR
Onc
WP

② Temple / Benman
Med Police
DDMAC
DSI

③ Flo Haun
BTG Talker
Radiopharm
Cytotoxic/DOA/anesth

④ Jenken
pulmonary
Encl
Repro

⑤ Kweeden
AI
IV
SP

⑥ Delap Bas
CTC
Derm + E7
Anth
Murphy
AD Peds

Questions for FDA/CDER Stakeholders

Based on a series of well-attended public meetings held in August and September 1998 to obtain public views on how FDA can meet its statutory obligations, the FDA published a plan for complying with our obligations under FDAMA, FDA Plan for Statutory Compliance. (see FDA's web site, <http://www.fda.gov/oc/fdama/fdamapln>.) Thoughtful and careful analysis of both stakeholder comments and the Commissioner's priorities revealed the emergence of two underlying themes: (1) strengthening FDA's science base and setting risk-based priorities, and (2) improving communication processes to increase transparency.

To help stakeholders focus their responses at the upcoming Stakeholder meetings, FDA requests that stakeholders address the five questions below in their oral and/or written views regarding how the agency can best strengthen its science base and improve risk-based communication. Additional information is available in the Federal Register Notice of March 19, 1999, can be obtained on the FDA website <<http://www.fda.gov>>.

Stakeholders are also encouraged to submit written responses in advance of the April 28, 1999 meetings. Written comments should be identified with docket number 99N-0386 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20851, e-mail "FDADockets@bangate.fda.gov" or via the FDA web site "<http://www.fda.gov>".

1. Science-based decisions are made throughout the life span of products from initial research, development and testing, through production, marketing and consumption. These decisions require the best science to identify, evaluate and balance product risks and benefits. It is crucial that FDA's staff in collaboration with product sponsors develop a shared understanding of new science and technologies and their effect throughout a product's life span. **What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?**
2. As the agency attempts to meet its public health responsibilities, the speed of discovery results in an avalanche of new information from government, academic and industry scientists. **What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a products life cycle?**
3. Most products in the American marketplace, especially medical ones, have two facets. On one side they benefit users and often improve lives. They are, however, rarely without risk, and their use can result in known and unknown side effects. Consumers must weigh benefits and risks before using these products, oftentimes with incomplete information. **What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?**
4. The Agency stated in the FDA Plan for Statutory Compliance, that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities. Because the Agency must allocate its scarce resources to achieve the greatest impact, **what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?**
5. FDAMA requires the agency to continue to meet with stakeholders on key issues. Meetings have ranged from explaining the positions of the agency on particular issues to working with sponsors on product applications. Historically, these interactions have benefited both stakeholders, through better knowledge of the FDA, and the agency, by leading to positive changes in its operations. Because the Agency wants to assure that its stakeholders are aware of and participate in its modernization activities, **what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?**

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