

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	10-24-01
Publication Date	10-25-01
Certifier	<i>[Signature]</i>

Request for Participants at the Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting names of qualified persons to participate on the Process Analytical Technologies Subcommittee (the Subcommittee) of the Advisory Committee for Pharmaceutical Science. The Subcommittee will identify and report to the Advisory Committee for Pharmaceutical Science on scientific issues related to application and validation of online process technologies such as near infrared and Raman spectroscopy and imaging methods for application in the manufacture of drug substances and drug products. The Subcommittee will also report on the potential benefits and risks associated with the application of these new technologies to public health and, as part of this analysis, evaluate the feasibility of the parametric release concept.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented and, therefore encourages recommendations of qualified candidates from these groups. Final selections from among qualified candidates will be based on the expertise demonstrated and previous experience with online process technologies.

DATES: All applications should be received by November 30, 2001.

ADDRESSES: Submit applications to David Morley (address below).

FOR FURTHER INFORMATION CONTACT: David Morley, Office of Testing and Research (HFD-900), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5186, FAX 301-827-3787, e-mail: morleyd@cder.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is seeking qualified persons to participate on the Process Analytical Technologies Subcommittee being formed under the Advisory Committee for Pharmaceutical Science. The Subcommittee will identify and report on the current state of technology, validation procedures, and the mechanistic basis of online process controls in both drug development and scaleup. These participants are not members of the Subcommittee and will not be voting on any issues, but they are encouraged to participate in the discussion of the issues. The Subcommittee will evaluate the potential for enhancing product quality and providing public health benefit.

II. Selection Criteria

Persons from government, industry, academia, and other organizations (such as research institutes) applying to participate on the Subcommittee should have exceptional accomplishments and be leading technical experts in the appropriate fields. In particular, expertise in application of the following scientific disciplines to pharmaceutical development and pharmaceutical manufacturing processes is desired: Process analytical chemistry, pharmaceuticals, industrial pharmacy, chemical engineering, pharmaceutical analysis, chemometrics, pattern recognition, computer expert systems, information technology, and statistics.

III. Application Procedures

Any interested person should submit appropriate biographical material and a list of scientific publications relevant to the Subcommittee to the contact person listed above.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: 10/17/01
October 17, 2001.

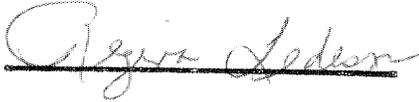


Linda A. Snyder,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL


Regina Lodeson