Concept Paper

Partnership with the University of Puerto Rico

Introduction

This document provides a brief summary to initiate discussions with the University of Puerto Rico (UPR) for research and training programs. These programs will assist hemispheric authorities and industries in promoting the development, registration, and approval of safe, effective therapeutic products for humans and animals, and safe and good quality foods. The document is intended to support initial planning between the US Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and the UPR for cooperative research and training activities for certain foods and therapeutic products. Links between this initial effort and other academic institutions, regulatory authorities, and industries in the Americas are envisioned.

Background

1. Promotion of Hemispheric Trade

The US encourages international trade and especially values trade with other nations in the Americas. Importation of FDA and USDA regulated products into the US must conform to applicable standards to meet the demands of the American public. FDA and USDA approaches to assure safe and good quality foods and therapeutic products are based on extensive domestic experience and are science based. Statutory and regulatory requirements for these types of products are complex and inevitably confusing to sponsors who wish to enter the American market. Training in US statutory provisions and regulatory requirements can assist firms and sponsors who wish to enter this market.

2. Enhancement of Regional/National Regulatory Systems

National and regional interests in the Americans reflect an increasing interest on the part of internal constituencies for safe, effective and good quality therapeutic products and safe and good quality foods. With suitable resources, the FDA and USDA have been willing to assist regional and national authorities and industries in understanding appropriate, rational approaches to meet these interests and objectives. A critical goal in this regard is to support local actions and to assure that the level of protection is as optimal as possible given inevitable resource constraints. With scarce resources even for domestic needs, FDA and USDA find it difficult or impossible to meet the needs of 30 or more countries in the

Americas on a continuing basis. Regional and hemispheric initiatives, coupled with local action, provide an opportunity to optimally utilize FDA and USDA resources and to achieve sustainability in appropriate local approaches. Universities in the Americas offer special opportunities for FDA and USDA staff to work with national scientists and educators and, in turn, with local authorities and industries. These efforts can focus on generation of information (research) to support local requirements and recommendations and to provide forums where interested parties--consumers, regulators, and industrial sponsors--can meet to develop rational and appropriate local approaches. National and regional laboratories, to assure good quality foods and medicines, may be considered in this initial discussion to promote strong hemispheric interactions.

3. Structures and Processes

Promotion of trade and harmonization of regulatory requirements to assure safe and effective medicines and good quality foods are of increasing interest to all countries in the Americas. For the most part, structures and processes to achieve these goals and objectives in the Americas are lacking, in contrast to Europe where regional harmonization is proceeding at a highly successful and accelerating pace. Work towards regional structures and processes in the Americas has been strengthened and promoted via activities of the Pan American Health Organization (PAHO), which is one of six regional organizations of the World Health Organization and the Food and Agriculture Organization of United Nations.

For example, PAHO plans and executes many training activities in the Americas and, more recently, has supported establishment of a Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization. Key activities of interest to this emerging organization include training in GMPs, quality of starting materials, compendial standards, national/regional control laboratories, bioavailabillity and bioequivalence, Good Clinical Practices, definitions for medical products, and food safety. The concept of working groups under this Steering Committee is being explored. For training and generation of information (research), links between the Steering Committee and academic institutions in the Americas may be especially useful to promote collaborations and leverage resources of the FDA and USDA.

Proposal for Discussion

The University of Puerto Rico presents several unique advantages:

- capability to conduct studies on research and training relative to the development, production, registration, and surveillance of good quality foods and medicines
- common language and culture with much of the Americas

- convenience of location and focus for the NAFTA region of the Americas
- fully accredited as a US academic institution

The purpose of the August 5, 1999, meeting at the University of Puerto Rico would focus on:

1. Scope/focus
2. Participants
3. Goals/objectives
4. Resources
5. Structures/processes

FDA and USDA need to anticipate the future and determine how to work collaboratively with international organizations and institutions of higher education to construct a future where their public health knowledge base continues to be recognized, respected, and accepted. Given adequate resources, FDA and USDA could disseminate information about their rational, science based regulatory systems to world regulators, especially in developing countries, via outreach activities. This could be accomplished with minimal impact on government resources, via collaborative initiatives with regional academic institutions, to create centers of excellence on specific regulatory topics.

Since the UPR is an academic institution with a Spanish curriculum in a US territory, it is the ideal site to pilot this concept. This institution offers a full curriculum in pharmacy and medicine, specifically tropical medicine. This allows FDA and USDA to explore the possibility of joint research in areas such as emerging pathogens, which thrive in the tropical climate.

Additionally, FDA and USDA recognize the need to tailor some of its initiatives to reach particular segments of the population. Thus, both Agencies would like to pursue activities with the UPR that will enable them to more effectively reach and provide services to the Hispanic/Latino community. There is a need to develop strategies and programs that will expose undergraduates and graduate students to the mission and work of both Agencies and at the same time encouraging the students to explore and possibly pursue careers in FDA or USDA.

Proposal:

The UPR could be a partner in pursuing research in areas that have confounded US import and export of FDA and/or USDA regulated products from countries of the Americas. Most of the current needs are in the food area, but concerns associated with drugs, devices and biologics are also increasingly possibility. Such concerns as emerging new pathogens or new vectors for pathogens,

toxicity of novel products, and differing needs and applications for pesticide controls in climates differing from the US, are examples of areas that currently need to be addressed in order to assure protection of the American consumer while fostering increased trade and other ties with the countries of the Americas.

Further, both agencies are finding an expanding need to disseminate understanding of existing requirements and policies to foreign trading partners in order to cultivate confidence in the safety and compliance of imported products. The seafood and meat HACCP regulations and the Good Agricultural Practices guidelines are recent examples where the agencies have identified the need for extensive outreach efforts to the Latin American countries. Again, it is here that the desire for enhanced trade is, in many cases, accompanied by less sophisticated growing, production, and handling controls or systems for assuring export of safe products. The ability of the UPR to establish, coordinate, and conduct training or information exchange sessions or workshops, using a common language and culture with our Latin American trading partners, is an opportunity that should not be overlooked.

The working relationship with the University can take any one of a number of forms. While the funding and granting of contracts for specific individual research tasks or training assignments could be negotiated, it would seem better to form some type of formal alliance or partnership with the University whereby the agencies, in cooperative exchange with the University, provides direction for needed research or training in order to address areas stemming from regulatory concerns. In this latter approach, the University will be in a position to solicit support from government and/or industry in those countries interested in promoting trade of products, about which the FDA and/or USDA have reservations. FDA and USDA could provide needed expertise on identified programs, which would generate mutual benefit.

Collaborative initiatives would help achieve common public health objectives and FDA and USDA could assure that global regulatory approaches of the 21st century correspond to its approaches. In so doing, the US can maintain and expand the current high level of public health protection provided to it s citizens and also help to extend this protection to the global community.

Recruitment in all areas: chemists, pharmaceuticals, other

Training: setting up curricula for GMPs , quality topics, all FDA not just CDER

OEA/Maritza, ORA, Offices of Compliance's in the various Centers

Quality: chemists, microbiologists, BA/BE experts in CDER, plus corresponding group in the other involved Centers, including CVM, CFSAN, AFIS (Kathy Wotecki/Tom Billie)

Research all FDA:

- CFSAN
  - JIFSAN and Moffett
  - Food pathogens
- CDER
  - PQRI
- CBER
  - NIH campus
- CVM
  - PQRI
- CDRH
  - Field laboratories, plus what goes in CDRH and elsewhere

Communications

PAHO Regulatory Steering Committee of the Americas
WHO—14 collaborating on product quality

University of Puerto Rico

School of Medicine/Department of Tropical Medicine
School of Pharmacy

District Office: Science Advisor (Chemistry Department member and wife works in School of Medicine, both work with President of University—many projects between University and US GOV)

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Background for meeting August 5, 1999