

to monitor and control disease outbreaks.

CDC's and FDA's respective missions to protect the public health may overlap in a variety of ways depending upon the subject matter. Each agency has a responsibility to work collaboratively to protect and improve public health. It may sometimes be the case that FDA or CDC will be in possession of information that could be useful to the other agency in that agency's performance of its responsibilities. Timely sharing of information between CDC and FDA is therefore critical to protecting the public health.

### III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

#### A. Coordination and Collaboration Relative to Public Health Activities

It is mutually agreed that:

1. Each agency will coordinate and collaborate with the other agency to protect and improve the public health. To achieve this, each agency will utilize the expertise, resources, and relationships of the other agency in order to increase its own capability and readiness to respond to emergency situations. In addition, each agency will designate central contact points where communications from the other agency, dealing with matters covered by this agreement, should be referred.
2. Each agency will participate in periodic joint meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for questions and problems that may arise.
3. Each agency will notify the other agency as soon as possible when issues of mutual concern become evident.
4. Each agency will collaborate with the other agency in all investigations of mutual concern. Such collaboration may include providing alerts to the other agency regarding disease outbreaks encountered as part of its activities; providing technical advice in areas of recognized expertise; providing results of analysis; making available expert witnesses; and exchanging information as described in section III B.
5. Each agency will consult with the other before issuing press or scientific releases or publications that may have a significant impact on the other agency.
6. Each agency will refer its proposed regulations, guidances, or recommendations that may have a significant impact on the other agency for review and comment by that agency before publication.
7. This agreement does not preclude CDC or FDA from entering into other agreements which may set forth procedures for special programs which can be handled more efficiently and expertly by other agreements.