CVM PROCEDURES ON MEDIA INQUIRIES

This document is designed to help CVM respond to media inquiries. By following these procedures, CVM employees will help the Center provide accurate and consistent statements to the press and the public and anticipate when Center-related stories will be published or broadcast.

Handling Media Inquiries to CVM

CVM employees who receive media inquiries should inform the Director of CVM's Communications Staff (or her back-up) before agreeing to an interview or to provide information to the media. Laura Alvey (HFV-12, 240-276-9109, laura.alvey@fda.hhs.gov), Director of CVM's Communications Staff, is the Center liaison with the FDA Office of Public Affairs on media issues, and she helps coordinate CVM's interaction with the media. Jon Scheid, CVM's Senior Writer Editor (240-276-9110, Jon.Scheid@fda.hhs.gov) is Ms. Alvey's back-up.

FDA's Office of Public Affairs (OPA) coordinates all interaction with the major media. Major media include newspapers in major cities and those with a national audience such as the *New York Times*, *Washington Post*, and *Wall Street Journal*. Also included in the category of major media are national magazines such as *Time* and *Newsweek*, news wire services such as the Associated Press (AP) and Reuters, and all radio and television stations (national or local.)

CVM's Communications Staff works with FDA's Office of Public Affairs to provide background information and to schedule any necessary interviews for CVM staff with major media.

Non-major media include trade press and newsletters and magazines published by professional societies and trade groups. Some examples of non-major media are *Feedstuffs*, *DVM NEWS*, and the *Journal of the American Veterinary Medical Association*. Non-major media inquiries are handled by CVM, and the Director of the Communications Staff or her back-up coordinate all interaction with non-major media.

Anticipating Media Interest in CVM Issues

CVM needs to anticipate issues that may be of interest to the media and be prepared by developing informative background materials. When appropriate, FDA will issue press releases, statements, or Talk Papers and CVM will issue CVM UPDATES and other materials to respond to the media. These materials provide FDA an opportunity to present important public health messages, announce significant initiatives, and provide information about new products of interest to the public.

Drug Approvals

Any ANADA or NADA with an approval letter intended for Dr. Sundlof's signature will be possible candidates for media materials. The primary Division Director and Generic Animal Drug Team Leader should notify the ONADE Office Director and Deputy Office Director, Cathy Beck, Tracey Forfa, Laura Alvey, and Jon Scheid by e-mail of an anticipated application approval at the time the draft package is forwarded to quality assurance (QA) for review. The notification should provide a one or two sentence summary of the subject of the application. For example:

> HFV-xxx submitted to the Quality Assurance for administrative review NADA xxx. This original New Animal Drug Application provides for a new molecular entity, xxx for use in the treatment of xxx. The product is the first xxx, and represents a new xxx.

Ms. Alvey or her back-up will ask the ONADE Office Director to contact the sponsor if a press release is warranted. Ms. Alvey or her back-up will handle all communications about drug approvals with FDA's Office of Public Affairs.

Significant Surveillance, Compliance, or Animal Feed Activities

Office of Surveillance and Compliance (OS&C) Division Directors or their back-ups should inform the OS&C Director or his back-up and the Director of the Communications Staff or her back-up about any significant activities in their area that are likely to be newsworthy to either the major or non-major media. For example, if the Center is planning a significant enforcement action, there is something unusual about Adverse Drug Experience (ADE) reports for a particular drug, or there is a major contamination problem in feed, the Division Directors should let the Communications Staff director know. OS&C employees who are aware of significant and possibly newsworthy activities should inform their Division Directors.

Office of Research Activities

Office of Research (OR) Division Directors or their back-ups should inform the OR Director or her back-up and the Director of the Communications Staff or her back-up about any important and potentially newsworthy activities in their area. For example, they should let the Director of the Communications Staff know about the publication of research articles about "hot topics" in journals or presentations on these topics at notable scientific meetings and conferences. OR employees who are aware of significant and possibly newsworthy activities in their areas should inform their Division Directors.