Correspondence from Members of Congress will receive high priority attention from all Food and Drug Administration (FDA) personnel. The Office of Legislation (OL) is responsible for replies to Congressional inquiries. In many instances, however, it is necessary for an incoming letter to be referred to the Center for preparation of a draft reply. Sometimes an inquiry is sent directly to the Center instead of through OL. Procedures for handling these inquiries are provided in this document. Additional information on the preparation of responses to Congressional inquiries is also provided in the FDA Staff Manual Guide (SMG) 2420.1.

NOTE: General Accounting Office (GAO), Inspector General (IG), House/Senate Appropriation requests and other Congressional inquiries related to budget are not “Congressional inquiries” as referred to in this policy. CVM has a separate routing process for these requests.

I. Purpose:

The purpose of this document is to describe the procedures to be used when responding to inquiries from members of Congress.

II. Congressional Inquiries Received from OL:

A. Congressional inquiries (via letter or telephone) initially received by OL and requiring CVM input will be directed to the Executive Programs Staff/Executive Secretariat (HFV-3) by the OL Correspondence Control Coordinator (HFW-10).

B. HFV-3 will send the original draft response to OL (HFW-10) electronically; and will copy the Center Management Team.

E. OL will then prepare the final response for issuance, providing copies to all offices specified on the draft.

III. Congressional Inquiries Received Directly by CVM Staff Members:

A. Letters:

1. Congressional letters and inquiries that are routed or sent directly to CVM staff members without going through OL shall be hand carried to HFV-3.
2. HFV-3 will provide the original incoming letter to HFW-10 for logging and jacketing, and HFV-3 will process as outlined above.

B. Telephone Inquiries:

1. All telephone inquiries from Congressional staff should be referred to the Executive Secretariat (HFV-3) who will coordinate the follow-up response with OL.

IV. Response Time Frame:

A. HFW-10 designates a due date for each Congressional inquiry transmitted to CVM for preparation of a draft response.

B. Every reasonable effort should be made to meet the designated due date.

C. If the due date cannot be met, HFV-3 must be notified prior to the due date, and the Executive Secretariat will request a time extension from HFW-10.