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# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL  
RUSSELL SULLIVAN, DEMOCRATIC STAFF DIRECTOR

December 19, 2005

## Via Electronic Transmission

Dr. Andrew C. von Eschenbach  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. von Eschenbach:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for drugs and medical devices. As Chairman of the Committee, I am greatly concerned by a special report published in the December 2005 issue of *Bloomberg Markets*, entitled, "Big Pharma's Shameful Secret" (Report). The Report states that "[e]very year, drug companies spend \$14 billion to test experimental substances on humans. Across the U.S., the centers that do the testing—and the regulators who watch them—allow scores of people to be injured or killed."

In the Report, SFBC International (SFBC) was identified as the largest for-profit drug testing center in North America. The Report raised several concerns involving safety and research methods performed on human subjects at the SFBC Miami facility. In light of these revelations, the Committee has requested to speak to the Chief Executive Officer of SFBC.

In furtherance of the Committee's ongoing inquiry, I request that the Food and Drug Administration (FDA) provide the following documents:

- A list of all FDA inspections of SFBC testing centers including but not limited to facilities in Miami, Florida; Fort Meyers, Florida; North Wales, Pennsylvania; Princeton, New Jersey; Kenneth Square, Pennsylvania; Québec City, Québec, Canada; Montréal, Québec, Canada; Trois-Rivières, Québec, Canada; Richmond Hill, Ontario, Canada; and Barcelona, Spain. Responses to this request should include the dates of all inspections and any and all findings reported from such.
- Any and all FDA Form 483 issued to SFBC during the course of inspections at any of its facilities and SFBC's response(s) to such.

Thank you in advance for your cooperation in this matter. I appreciate your response to this inquiry no later than January 6, 2006.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley  
Chairman