SOCMA

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

0047 8 FEB -4 P12:37

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

February 4, 2008
Submitted Via Fax

Comments on the Food and Drug Administration Report of the Subcommittee on Science and Technology, entitled: "FDA Science and Mission at Risk"	)))))	Docket Number 2007N-0489

Synthetic Organic Chemical Manufacturers Association, Inc.

&

Bulk Pharmaceuticals Task Force

1850 M Street, N.W.
Suite 700
Washington, D.C. 20036
202.721.4100 www.socma.org
www.socma.com/BPTF

SOCMA

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

February 4, 2008
Submitted Via Fax

Comments on the Food and Drug Administration Report of the Subcommittee on Science and Technology, entitled: "FDA Science and Mission at Risk"	)))))	Docket Number 2007N-0489

Synthetic Organic Chemical Manufacturers Association, Inc.

&

Bulk Pharmaceuticals Task Force

1850 M Street, N.W.
Suite 700
Washington, D.C. 20036
202.721.4100 www.socma.org
www.socma.com/BPTF

Comments

The Synthetic Organic Chemical Manufacturers Association (SOCMA) and the Bulk Pharmaceuticals Task Force (BPTF) appreciate the opportunity to submit comments on the Food & Drug Agency's Science Board report: *FDA Science and Mission at Risk.*

SOCMA is the leading trade association for the specialty-batch chemical manufacturing industry and represents over 300 member companies. The BPTF is a subgroup within SOCMA representing the manufacturers of active pharmaceutical ingredients (API's). The manufacturers have both domestic and foreign facilities.

SOCMA and the BPTF applaud the Science Board's report recognizing the serious deficiencies within the FDA. This report is only one in a long string of reports demonstrating the inefficiencies of the Agency, its lack of focus on manufacturing quality, and poor internal management.

The report correctly points out the Agency's need of serious investment to overhaul its management, find new ways to retain quality staff, and inject new modes of thinking into how the Agency should carry out its mission.

However, SOCMA and the BPTF are disappointed the report did not adequately address a key issue facing the agency: the inspection of foreign facilities manufacturing active pharmaceutical ingredients (API's). While the report details the need for greater scrutiny of the development of new products and greater post-market surveillance ensuring the general safety of the manufactured drugs, it does not provide enough detail describing the need for inspecting the process of manufacturing drugs and their ingredients after the safety trials are completed and manufacturing is approved. This is particularly noteworthy for over the counter medications (OTC) and generics.

API manufacturing has exploded in foreign facilities, with 80% of all API's now imported in the United States[1]. Despite this large increase, the FDA has failed to react. There has been no corresponding increase of inspections of foreign facilities to match this explosion. According to the House Commerce Subcommittee on Oversight & Investigations[2], most of the foreign inspections are performed on average, in three days or less to maximize the inspectors' time "in-country", with the inspections named in advance. This is juxtaposed to US firms that are inspected on average for a week and must undergo what are usually surprise inspections every two years.

This is why SOCMA and the BPTF believe that all facilities – regardless of location - need to be evaluated within the same risk scale, with foreign facilities being considered a higher risk. This would force the FDA inspection regime to concentrate its efforts on the worst actors, whether they are domestic or abroad.

---

[1] GAO/HEHS-98-21: General Accounting Office, Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Commerce, House of Representatives, Food & Drug Administration, *Improvements Needed in the Foreign Drug Inspection Program* (March 1998)

[2] US house Committee and Energy and Commerce Subcommittee on Oversight and Investigations – Staff Trip Report – *FDA Inspection Program: A System at Risk* (October 30, 2007)

Additionally, the FDA is unable to accurately state the number of firms importing API's into the United States. The current information technology infrastructure is so poorly conceived that there are no real accurate numbers. There are multiple databases making it difficult, if not impossible to measure accurate ongoing resource needs[3]. As the FDA Science Committee Report indicates, these issues have been the subject of numerous reports, hearings, and media scrutiny for a number of years, with the problem only getting worse. The FDA is virtually flying blind on inspections matters, its activities are perfunctory at best, and without greater resources, new approaches and better management, the problems will grow only greater still.

The report is enlightening in its demonstration that the FDA is unprepared to deal with the new realities of the global marketplace and the global supply chain. With the new science that is forming along a cross-disciplinary approach, the FDA will need to tackle issues that it has never before seen: biotechnology, nanotechnology, and human genome manipulation. The FDA must confront these issues not only in terms of safety and the new drug's success rate, but also how the drugs will be manufactured.

As the report demonstrates, the Agency is woefully unprepared to deal with this new era. It uses last century tactics for a new millennium challenge. One issue is clearly the lack of funding: the agency desperately needs more money to tackle the obvious need for more overseas inspections. It also needs to use the money it does have in a more effective manner in terms of how it conducts inspections and the performance of the IT infrastructure.

FDA staff performing foreign inspections must have better preparation before going overseas. They need to understand the health risks associated with the emerging markets, understand the nation's culture as it applies to language and to business. The FDA should consider opening offices in other nations to work with those nations on improving their own inspection programs and performing perfunctory inspections of facilities exporting into the United States. This would allow the US to certify other nations' inspection regimes with possible benefits being speedier access to US markets. It has recently been reported that the FDA is intending to open offices in China and India. SOCMA and the BPTF support this idea, which we view as a good first step.

We also support the efforts of the FDA's Science Committee to encourage the FDA to work with the private sector in establishing criteria and plans that will result in greater monitoring of foreign manufactured products. Through private sector/ FDA cooperation, the FDA would gain a greater understanding of the market forces working within the industry and how the FDA can better use and improve its available resources.

This report should leave no doubt to the FDA that innovative thinking is required at the Agency. SOCMA and the BPTF do not claim to have all the answers, but believe that innovation needs to be at the heart of any FDA action going forward.

SOCMA and BPTF are hopeful and encouraged by the FDA's recent trips to and discussions with China and India. These two nations play a huge role in supplying pharmaceutical

[3] US house Committee and Energy and Commerce Subcommittee on Oversight and Investigations Hearing – Chairman Bart Stupak Opening Statement on Staff Trip Report – *FDA Inspection Program: A System at Risk* (November 1, 2007)

ingredients to this nation and the rest of the world. But these meetings must deliver a rational and workable plan for rectifying the quality issues of emerging markets. They need to be the beginning of an open and honest dialogue about the nature of regulation and the need for quality products. Memorandums of Understanding (MOU's) should not replace on-the-ground inspections until those nations are capable and committed to a US style inspection.

The FDA should also consider pursuing cooperative arrangements, such as mutual recognition agreements, with competent foreign authorities that meet US inspection standards. These agreements could potentially extend overseas API inspection coverage of higher risk facilities and allow the FDA to reallocate resources for other vital Agency needs.

Finally, the departure of key staff is disturbing and cause for alarm. The agency is facing increasing responsibilities, more technical subject matter, and the need for more resources. The FDA must look to new ways to encourage staff to stay, whether through greater professional development opportunities, greater pay, and better promotional structure similar to the private sector.

* * * * * * * * * * *

In conclusion, SOCMA and the BPTF agree with the Science Board report: without greater resources, retention of staff, significant infrastructure investment, a concentration on risk-based scenarios, and new innovative ways of thinking, the consistent problems will persist. But they will grow and only at the risk of the health and safety of the US consumer. We offer our support, the safety of the American public is at risk, and we all need to work together.

We look forward to working with the FDA and the Science Committee on these issues. For further information, please contact Gregory Minchak, Manager Public Relations & Communications, at SOCMA, at 202-721-4100.

Respectfully Submitted,

Joseph Acker
President
Synthetic Organic Chemical Manufacturers Association