

SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES

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SOCMA's BPTF and CEFIC's EFCG Work with FDA to Protect Public Safety

Washington, DC – In a move to better protect public safety, SOCMA's [Bulk Pharmaceutical Task Force \(BPTF\)](http://www.socma.com/PressRoom/index.cfm?subSec=12&articleID=668) (<http://www.socma.com/PressRoom/index.cfm?subSec=12&articleID=668>) and [European Chemical Industry Council's Fine Chemicals Group \(EFCG\)](http://efcg.cefic.org/) (<http://efcg.cefic.org/>) are calling on the Food and Drug Administration (FDA) to mandate inspections of foreign Active Pharmaceutical Ingredient (API) manufacturing sites, with the cost borne by those sites being inspected. Both organizations have indicated a willingness to pay fees for these inspections when performed on their member-owned facilities outside the U.S.

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(<http://click.icptrack.com/icp/relay.php?r=10171978&msgid=215500&act=QV6Z&c=156937&destination=http%3A%2F%2Fwww.socma.com%2Fassets%2Ffile%2Fsocma1%2FPDFfiles%2Fbptf%2FGeneric-Medicines-User-Fee-Comments-2-18-11.pdf>) recently submitted to the Agency, BPTF and EFCG argued that the FDA is unable to keep up with globalization of the drug industry. As a result, inspections in high-risk regions like China and India are almost non-existent when compared to the U.S. and Europe, posing a risk to public health.

In order to have a sustainable foreign inspection program, a fee for each foreign compliance inspection carried out by Agency should be collected.

BPTF and EFCG also called for the development of an electronic database to capture accurate information on API manufacturers selling product into the United States. Registration fees, sufficient to cover the cost of developing, compiling and maintaining this database were suggested. Having accurate information about API manufactures is critical to ensuring a safe drug supply.

BPTF and EFCG are sector groups of SOCMA and CEFIC respectively, whose members include manufacturers of active pharmaceutical ingredients (APIs), excipients and intermediates. One of the primary objectives of both groups is to interact with government agencies on emerging issues that affect members.

For more information, please contact: Guy Villax, EFCG, Gvillax.ia@hovione.com or John DiLoreto, BPTF, DiLoretoJ@SOCMA.com.

For information on BPTF, or topics relating to current good manufacturing practices of APIs, please visit: www.socma.com/bptf.

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About CEFIC

CEFIC is the leading trade association of the chemical industry in Europe representing 29,000 large, medium and small companies, which provides 1.3 million jobs and accounts for one third of the world's chemical production.
<http://www.cefic.org/>

About SOCMA

SOCMA is the only U.S. based trade association dedicated solely to the batch, custom and specialty chemical industry. Since 1921, we have represented a diverse membership of small, medium and large chemical companies, making us the leading authority on this sector. SOCMA has a global membership of more than 200 companies. For more information on our services and products, please visit www.socma.com.

ChemStewards® is SOCMA's flagship environmental, health, safety and security (EHS&S) continuous performance improvement program. ChemStewards was created from industry's commitment to reducing our environmental footprint. Industry created ChemStewards to meet the unique needs of the batch, custom, and specialty chemical industry. As a mandatory requirement for SOCMA members engaged in the manufacturing or handling of chemicals, ChemStewards is helping participants reach for superior EHS&S performance. To learn more visit www.chemstewards.com.