

**Ciba Specialty Chemicals Corporation**  
**Ciba® Expert Services**

Michael Ruberto, Ph.D.

Head of Regulatory Services, NAFTA  
Expert Services

540 White Plains Road

Tarrytown, NY 10591-9005

E-mail: michael.ruberto@cibasc.com

Tel: 914-785-2892 Fax: 914-785-4147



December 15, 2006

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20857

RE: Docket No. 2006N-0464

Ciba Specialty Chemicals Corporation would like to submit the following comments in regards to Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing.

1. Transition from Paper Submissions to Electronic Submissions:

At present, Ciba Specialty Chemicals has only submitted paper Food Contact Notifications.

There are obstacles that have hindered Ciba from submitting entirely electronic FCN's. The major obstacle is some of the supporting documentation is not always readily available in electronic formats (i.e. raw data (such as chromatograms and spectra), toxicological studies and analytical reports). Documents which are not available electronically have to be scanned. In some cases, scanned copies do not have the same image quality as the original or a photocopy, which can make data/information interpretation difficult.

2. Cost

The cost can be divided into man-hours and materials costs. The man-hours, from a cost perspective, needed to prepare and electronic FCN would approximately equal the time needed to prepare a paper FCN. However, if the proposed electronic

2006N-0464

C2

format would include submissions via e-mail and/or on a storage media such as a CD/DVD, the cost of preparing an electronic FCN would be significantly less than that needed for 5 paper copies.

### 3. Time

Time could be equated to cost in this regard and the comments in section 2 would apply.

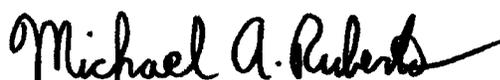
From a technology and capability perspective, Ciba Specialty Chemicals is presently capable of preparing and submitting entirely electronic FCN's, if the scanning of hard copy documents is deemed to be acceptable.

### 4. Implementation

The current format of the FDA Form 3480 is not adequate for FDA electronic submission. The document formatting is locked and password protected. This then does not allow for insertion of any non-text entries. The option to insert information, such as, structures, reaction schemes and information other than text into the form is not available. As a result, attachments to form need to be used, which increase the complexity required to assemble and format an electronic Food Contact Notification.

Should you have any questions, please do not hesitate to contact the undersigned at (914) 785-2892, or e-mail at [michael.ruberto@cibasc.com](mailto:michael.ruberto@cibasc.com).

Best regards,

A handwritten signature in black ink that reads "Michael A. Ruberto". The signature is written in a cursive style with a long, sweeping underline.

Michael Ruberto, Ph.D.