

Gross, Mary

From: Robert Schubene1 [r.schubene1@EAN.CH]
Sent: Friday, July 05, 2002 9:39 AM
To: 'grossm@cder.fda.gov' (1) 7/16 '02 AUG 12 11:20
Subject: FW: email to Food and Drug administration
Importance: High

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration
 21 CFR Parts 201, 211, and 601, [Docket No. 02N-0204]
 Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting

Dear Mrs. Gross,

My name is Robert A. Schubene1 and I am the CEO of the EAN standards organisation in Switzerland. It is with great interest, that I have followed the FDA proposed rule to mandate bar-coding of pharmaceutical and biological products. Such a rule will have great affect here in Switzerland and has lead to some discussion with major manufactures like Novartis, Roche, Ciba etc. These companies as well as all the other 286 pharmaceutical companies will heavily be affect theis new rule, as they shipt healthcare products to the United States.

I will not be able to attend the July 26, 2002 meeting but I want to go on record with my organisations view on this matter.

The EAN.UCC system is the world standard for product and process marketing. It is used in 23 industries, 104 countries and has over a million members. The majority of healthcare companies use this system and in our country its use is enforced by law in the case of processing narcotic substances. Furthermore UNDCP has signed an agreement with EAN International in order to the EAN system for the control of the flow of narcotic substances on a global level.

It is our strong recommendation that the FDA adopt the EAN.UCC system as its own. Such an adoption will keep overall costs down for global healthcare and quickly achieve your aim of medication reduction, not only in the USA but worldwide. To select otherwise would add tremendous cost to an already overburdened healthcare delivery network and have negative commercial effects outside the United States.

With kind regards

Robert A. Schubene1
CEO EAN (Switzerland)

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