

Gross, Mary

WRITING

From: Jim.Bracken@ibec.ie  
Sent: Friday, July 12, 2002 12:08 PM  
To: grossm@cder.fda.gov  
Subject: Unit Dose bar code labelling

Dear Mary,

I am Jim Bracken of EAN Ireland, the local EAN standards organisation based in Dublin, Ireland.

I have followed with great interest the FDA proposed rule to mandate bar-coding of pharmaceutical and biological products. Such a rule will have great affect here in Ireland and throughout the EU of which we are a member state. Ireland has 65 US Pharmaceutical companies manufacturing healthcare products for sale and distribution throughout the EU and other parts of the World.

Whilst I am not able to attend the July 26, 2002 meeting, I do want to go on record with my organisation's 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. 5 billion EAN.UCC bar codes are scanned every day worldwide. The vast majority of healthcare companies use this system. It is our strong recommendation that the FDA adopt the EAN.UCC system as its own. Such an adoption will help to reduce overall costs for global healthcare and quickly achieve your aim of medication reduction and also lessen significantly the risk of medication errors which are an an unacceptable level, 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.

Yours sincerely,

Jim Bracken  
Director  
EAN Ireland

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