The Elsmar Cove Forum (*http://Elsmar.com/Forums/index.php*)
- US Food and Drug Administration (FDA) (*http://Elsmar.com/Forums/forumdisplay.php?f=151*)
- -

Use of Symbols on Medical Device Labels - FDA Requirements

(*http://Elsmar.com/Forums/showthread.php?t=48952*)

adv_webdev 22nd June 2011 03:01 PM

Use of Symbols on Medical Device Labels - FDA Requirements

Hi,
We make medical devices (non-IVD, class 2, some 1) that sell in US as well as in EU and other international markets.FDA require that we explain all the symbols in English Text - this might create a problem when we market this in Europe as all non-english text on the label will need translation. This will end up in making the label too large for the product packaging to hold.How are you working around this issue for your products?

Any suggestions greatly appreciated.
P.

P.S. In the past, FDA was agreeable to having the explanation of symbols in the IFU (labelling). Now, the scrutiny is much stricter and they are requiring this on the label.

rclanzillotto 22nd June 2011 04:11 PM

Re: Use of Symbols on Medical Device Labels - FDA

If the symbols are harmonized i.e in accordance with EN 980, then no translation or accompanying text is needed. Good luck

adv_webdev 22nd June 2011 04:24 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***rclanzillotto*** (Post 439491)
If the symbols are harmonized i.e in accordance with EN 980, then no translation or accompanying text is needed. Good luck

Thanks for your response. Can you point me to a regulation/guidance doc. that says that EN 980 symbols are acceptable to FDA for non-IVD devices?

treesei 22nd June 2011 05:14 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***adv_webdev*** (Post 439493)
Thanks for your response. Can you point me to a regulation/guidance doc. that says that EN 980 symbols are acceptable to FDA for non-IVD devices?

I am not familiar with EN 980 but ISO 15223 is recognized by FDA.

http://www.accessdata.fda.gov/script...ds/results.cfm

adv_webdev 22nd June 2011 06:54 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***treesei*** (Post 439500)
I am not familiar with EN 980 but ISO 15223 is recognized by FDA.

http://www.accessdata.fda.gov/script...ds/results.cfm

ISO 15223 does not declare any symbol as a known symbol (unlike EN 980) and exempt them from explanation in the IFU. Thanks for the link, though. I didn't know about this.

My actual question is this: Since FDA requires text explanation of symbols on labels and all of EU requires all English text to be translated in all regional languages, how can you put all the information in the small available space on a label? Do you have separate labels for US and EU or you use some other method to balance these two requirements?

P.

rclanzillotto 22nd June 2011 09:05 PM

Re: Use of Symbols on Medical Device Labels - FDA

I would not give up on defining the symbols in the translated user guide for Europe. If this is what ISO 15223 allows you to do then it is clear. If ISO 15223 is not clear with respect to it..then your answer lies in Risk Management IMHO

Dudes

23rd June 2011 04:30 AM

Re: Use of Symbols on Medical Device Labels - FDA

FDA does require more and more often that all symbols are explained in "english wording".

To avoid any problems with your packaging for the rest of the world, one way of proceeding is to put the explanation on a separate label. This is acceptable for FDA. English wording has to be on the outside of your packaging, but there is no requirement that it should be on the same label.

You can for example have a label with the distributor (also required) and explanation of the symbols.

adv_webdev

23rd June 2011 05:35 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by* ***Dudes*** (Post 439559)
> *FDA does require more and more often that all symbols are explained in "english wording".*
>
> *To avoid any problems with your packaging for the rest of the world, one way of proceeding is to put the explanation on a separate label. This is acceptable for FDA. English wording has to be on the outside of your packaging, but there is no requirement that it should be on the same label.*
>
> *You can for example have a label with the distributor (also required) and explanation of the symbols.*

There is one problem, though. There is no way to specify that products distributed in US will have this additinal sticker exclusively. If we apply this sticker on all product, then we need to provide translation for the English text, if it gets sold in EU. So, would you suggest having all the translations on another sticker as well?

AnaMariaVR2

23rd June 2011 06:37 PM

Re: Use of Symbols on Medical Device Labels - FDA

Simbologia etichetta del prodotto

in Italian

MIREGMGR 23rd June 2011 07:07 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by **adv_webdev*** (Post 439482)
> *We make medical devices (non-IVD, class 2, some 1) that sell in US as well as in EU and other international markets.FDA require that we explain all the symbols in English Text - this might create a problem when we market this in Europe as all non-english text on the label will need translation. This will end up in making the label too large for the product packaging to hold.How are you working around this issue for your products?*

We make hundreds of products with classifications like yours, for US-and-EU sale under our name and the names of many US and European OEMs. For that latter group of customers, we are the regulatorily responsible Manufacturer and our customer is a distributor. In all such cases, we use EN 980/ISO 15223 symbology on the label, with English-only subtext for each symbol in a small but readable font size. We have been doing this for a number of years now, and have had no objection from US FDA, our NB, our Authorized Representative, authorities in Europe, or end users.

adv_webdev 24th June 2011 04:45 PM

Re: Use of Symbols on Medical Device Labels - FDA

Thank you, this is good to know.

P.

A.I.C 17th October 2011 08:54 AM

Re: Use of Symbols on Medical Device Labels - FDA

1 Attachment(s)

Quote:

> *In Reply to Parent Post by **MIREGMGR*** (Post 439700)
> *We make hundreds of products with classifications like yours, for US-and-EU sale under our name and the names of many US and European OEMs. For that latter group of customers, we are the regulatorily responsible Manufacturer and our customer is a distributor. In all such cases, we use EN 980/ISO 15223 symbology on the label, with English-only subtext for each symbol in a small but readable font size. We have been doing this for a number of years now, and have had no objection from US FDA, our NB, our Authorized Representative, authorities in Europe, or end users.*

Very interesting info, I would also like to use this method on our product but have been warned to do so since the older EU member countries (e.g. France and Germany) might object if there is only English subtext, even though it is combined with symbols from SS-EN 980/ ISO 15223. So this makes me wonder if:

- Does your distributes sell all over Europe?
- Did you have to take any discussions with the Regulatory Authorities of any of the EU countries regarding the labeling?
- Are you using only symbols from these standards or do you also have designed own symbols?

The GHTF guidance doc states that:
"Provided that safe and correct use of the device is ensured, a RA may authorize labeling to be in one or more language(s) than other than its national language(s)" (attachment page 8) So obviously there is some support to use only English subtext, the question is how strict the different RA in Europe are?

MIREGMGR

17th October 2011 09:12 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by* ***A.I.C*** (Post 454401)
> *Does your distributes sell all over Europe?*

Distributors selling the product under our name do cover most of the EU/EEC countries, but possibly not all of them.

The regional affiliates of the multinational OEMs that distribute private-labeled versions of our products do distribute in all such countries.

Quote:

> Did you have to take any discussions with the Regulatory Authorities of any of the EU countries regarding the labeling?

We've had no such direct discussions. Our only interaction other than with our distributors and end users has been with our NB and our Authorized Representative. As a company located outside the EU, all interactions with the national Regulatory Authorities are handled by our Authorized Representative. We have reason to believe that our Authorized Representative is very rigorous about compliance with the various rules and guidances. We haven't directed them to have any such discussions, and they haven't informed us of having had any such discussions.

Quote:

> Are you using only symbols from these standards or do you also have designed own symbols?

Mostly the former, but some labels have one or two non-standardized information-only (i.e. non-warning, not necessary for safe and effective product use) symbols as well.

Bonebuilder

5th December 2011 03:51 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***adv_webdev*** (Post 439506)
ISO 15223 does not declare any symbol as a known symbol (unlike EN 980) and exempt them from explanation in the IFU. Thanks for the link, though. I didn't know about this.

My actual question is this: Since FDA requires text explanation of symbols on labels and all of EU requires all English text to be translated in all regional languages, how can you put all the information in the small available space on a label? Do you have separate labels for US and EU or you use some other method to balance these two requirements?

P.

Hi adv_webdev

Is your first statement correct?

The scope of 15223-1 seems otherwise, quote;

Quote:

Scope
This part of ISO 15223 identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of ISO 15223.

MIREGMGR 5th December 2011 08:55 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

...all of EU requires all English text to be translated in all regional languages...

My employer's understanding based on many years experience is that in practice, European authorities (and knowledgeable quasi-authorities such as notified bodies and authorized representatives) first look for a standardized symbol that communicates a particular information-element. If such a symbol is present, then English text below and accompanying that symbol and in a font substantially smaller than the symbol is tolerated, because of the regulatory understanding that US FDA has not yet harmonized regarding label symbols.

This is purely *de facto*. I know of no written statement of such a practice. But, we see it in effect in the marketplace every day.

Bonebuilder 5th December 2011 09:10 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by* ***MIREGMGR*** (Post 461011)
> *My employer's understanding based on many years experience is that in practice, European authorities (and knowledgeable quasi-authorities such as notified bodies and authorized representatives) first look for a standardized symbol that communicates a particular information-element. If such a symbol is present, then English text below and accompanying that symbol and in a font substantially smaller than the symbol is tolerated, because of the regulatory understanding that US FDA has not yet harmonized regarding label symbols.*
>
> *This is purely de facto. I know of no written statement of such a practice. But, we see it in effect in the marketplace every day.*

But where is the FDA requirement to have text coming from?

21 CFR 801.15.c1 perhaps?

If they recognise ISO15223 which they do, both parts, Recognition Numbers 5-59 & 5-61 for part 1 and 5-56 for part 2

Which has precedent?

MIREGMGR 5th December 2011 09:58 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by* ***Bonebuilder*** (Post 461023)
> *But where is the FDA requirement to have text coming from? 21 CFR 801.15.c1 perhaps?*

Yes.

Quote:

> If they recognise ISO15223 which they do, both parts

Two comments:

1. The "recognition" process is at the guidance level. 21 CFR 801.15.c1 is law. In a conflict instance, the law always governs.

2. The use of symbols is recognized only for 25 specific symbols, and only for the limited case of professional-use IVDs. For all other device types and markets, symbols are not recognized. See guidance "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended For

Professional Use".

skime 5th March 2013 01:13 PM

Re: Use of Symbols on Medical Device Labels - FDA

We have similar question regarding symbols, the "do not use if package is damaged". ISO 15223-1:2012 calls out "In Europe, this symbol shall be expalained in the information supplied by the manufactruer" The FDA does not appear to recognze this symbol. We have limited space availble on the product and we do not use IFU's. We are exploring the option of English "Do not use if packaged is damaged" adjacent to the symbol, recongizing the absence of other languages due to space constraints. The label will be marketed US and EU. Comments?

wangyang 20th March 2013 09:55 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***MIREGMGR*** (Post 461029)
Yes.

Two comments:

1. The "recognition" process is at the guidance level. 21 CFR 801.15.c1 is law. In a conflict instance, the law always governs.

2. The use of symbols is recognized only for 25 specific symbols, and only for the limited case of professional-use IVDs. For all other device types and markets, symbols are not recognized. See guidance "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended For Professional Use".

Unfortunately, FDA now is much more strict to the symbol use.

We used to print the symbol and the English explanation of the symbol on the label, and it is accepted by FDA reviewer, however, in our recent submission, FDA reviewer request us to delete the symbol, even there is explanation of the symbol on the label. I am just discussing with them and don't know the result. :confused:

Bonebuilder 21st March 2013 07:00 AM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

In Reply to Parent Post by ***wangyang*** (Post 514604)
Unfortunately, FDA now is much more strict to the symbol use.

> *We used to print the symbol and the English explanation of the symbol on the label, and it is accepted by FDA reviewer, however, in our recent submission, FDA reviewer request us to delete the symbol, even there is explanation of the symbol on the label. I am just discussing with them and don't know the result. :confused:*

Thanks for your comments

Did your reviewer give you a reason why they wouldn't allow symbols? We have similarly had devices accepted where the labels have symbols with test alongside.

Are FDA saying that labels have to be dedicated to US only? Surely that goes against the remit of "least burdensome" route to market, or am I just being naive?

MIREGMGR 21st March 2013 10:06 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Inconsistency sometimes occurs in FDA reviews.

I don't know of any documented basis for FDA to request removal of symbol content from labeling if that symbol content is closely coupled to English text content that communicates the same message.

FDA has according semi-recognized status to past GHTF guidances, and GHTF/SG1/N70:2011 allows (and recommends) the use of symbols by themselves, without a need for explanatory English subtext, as long as the symbol's meaning is clear to the intended user. This of course conflicts with existing FDA guidances, but certainly would seem to oppose a reviewer going beyond the text of those existing FDA guidances in the opposite direction.

I don't interpret any of the primary FDA guidances on labeling to prohibit presence of content in addition to the required content, as long as that extra content does not mislead the intended user. In past instances of which I'm aware, symbols with fully explanatory English subtext of sufficiently prominent and readable typesize to explain the symbol meaning have not been considered misleading to the intended user.

If your reviewer is stubborn on this, you could consider appealing that point to the next review level. FDA in the past has been willing to cooperate when a device is to be label for global sales, involving conformance to multiple regulatory authority requirements, when the Manufacturer can show a reasonable effort to support safety and effectiveness via their labeling approach.

wangyang 21st March 2013 08:39 PM

Re: Use of Symbols on Medical Device Labels - FDA

Quote:

> *In Reply to Parent Post by* ***Bonebuilder*** (Post 514653)
> *Thanks for your comments*
>
> *Did your reviewer give you a reason why they wouldn't allow symbols? We have similarly had*

devices accepted where the labels have symbols with test alongside.

Are FDA saying that labels have to be dedicated to US only? Surely that goes against the remit of "least burdensome" route to market, or am I just being naive?

I agree with you and i try to discuss with them

wangyang 21st March 2013 08:42 PM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Quote:

In Reply to Parent Post by ***MIREGMGR*** (Post 514689)
Inconsistency sometimes occurs in FDA reviews.

I don't know of any documented basis for FDA to request removal of symbol content from labeling if that symbol content is closely coupled to English text content that communicates the same message.

FDA has according semi-recognized status to past GHTF guidances, and GHTF/SG1/N70:2011 allows (and recommends) the use of symbols by themselves, without a need for explanatory English subtext, as long as the symbol's meaning is clear to the intended user. This of course conflicts with existing FDA guidances, but certainly would seem to oppose a reviewer going beyond the text of those existing FDA guidances in the opposite direction.

I don't interpret any of the primary FDA guidances on labeling to prohibit presence of content in addition to the required content, as long as that extra content does not mislead the intended user. In past instances of which I'm aware, symbols with fully explanatory English subtext of sufficiently prominent and readable typesize to explain the symbol meaning have not been considered misleading to the intended user.

If your reviewer is stubborn on this, you could consider appealing that point to the next review level. FDA in the past has been willing to cooperate when a device is to be label for global sales, involving conformance to multiple regulatory authority requirements, when the Manufacturer can show a reasonable effort to support safety and effectiveness via their labeling approach.

Thank you for your help. I have never think of appealing to the lead reviwer. Does it work?

Bonebuilder 22nd March 2013 05:05 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Yes absolutely. A reviewers role is to administer the regulations, not to interpret them.

skime 26th March 2013 10:25 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Thank you for the replies.

We have encountered contradictory FDA interpretation of label symbols as well. In a 510k application the reviewer did not recognize any symbols.

When confronted with the FDA site that calls out recognized symbols the reviewed claimed that the 510k reviewer section did not recognize symbols.

Needless to say this makes life difficult to meet two opposing standards!!!

MIREGMGR 26th March 2013 10:44 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Quote:

> *In Reply to Parent Post by* ***skime*** (Post 515242)
> *In a 510k application the reviewer did not recognize any symbols.*

Per current guidance, in general symbols are not accepted by themselves (i.e. without English-language subtext), except for certain professional-use IVDs.

The acceptance is of the presence of symbols (i.e. not objecting to their being on the labeling), but not their utilization as communication elements; that communication instead being provided by English-language subtext that closely accompanies each such symbol.

mscottf 27th March 2013 08:30 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

I am very interested in this discussion as we have a non-IVD that has attained CE Mark and will be submitted to FDA in the next year. For the EU, most text was removed from the labels and all symbols are harmonized symbols from ISO 15223-1 or ISO 7000.

I am concerned about the possible need to add small text to each symbol and then have to maintain separate labeling for EU and US, or put the text on a separate label.

i just noticed that in ISO 15223-1, section 4.2, Requirements for Usage; under Note 3, it states: Symbols may be used without accompanying text. Where regulations require accompanying text, the title of the symbol given in this part of ISO 15223 should be considered sufficient.

If the FDA does in fact recognize ISO 15223-1, does this provide the coverage for not using text, or does the FDA still require it in spite of this? If so, would not just the title suffice?

MIREGMGR 27th March 2013 09:44 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Quote:

> *In Reply to Parent Post by* ***mscottf*** (Post 515335)
> *If the FDA does in fact recognize ISO 15223-1, does this provide the coverage for not using text, or does the FDA still require it in spite of this? If so, would not just the title suffice?*

My experience has been that FDA is not internally consistent regarding this. ISO 15223-1 is included in the List of Recognized Standards; however, legacy labeling guidances remain in force, and do not recognize the use of symbols (except for professional use IVDs). My understanding is that FDA's stance is that if a symbol is present on labeling, even though FDA will not recognize that symbol unless it's accompanied by subtext, the symbol must be consistent with 15223 if possible so that it doesn't miscommunicate; and this is why 15223 is included in the Recognition List.

Obviously there's a conflict between the EU multi-language requirement and the FDA English-language-subtext requirement. The company for which I work makes many products that are distributed globally. We provide symbols for world use except in USA, and English subtext for USA. So far, this approach has been acceptable to FDA, our NB, and the other world regulatory bodies with which we have come into contact.

As to what the English subtext wording should be, our approach is to use expressions that we think are consistent with common USA clinical terminology. I actually haven't reviewed them against the standard, but they're probably consistent. I'd expect some differences because (AFAIK) the standard is written in British or European English, which has some terminology and spelling differences from common American English.

mark walker

3rd April 2013 04:35 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

You would be crazy to use text on warning labels for translation purposes, symbols where possible. If You have no option You have to make specific kits for specific countries..

Ab\nother variable is comparing 3rd edition requirements for labeling with the requirements of IEC82079-1.

iN Europe itself 15233 was published as harmonised and then withdrawn and en980 was re-instated.:rolleyes:

Bonebuilder

3rd April 2013 05:13 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Sorry Mark

In this dynamic, some would say confusing, world of standards you're behind the times.

EN 980:2008 "Symbols for use in the labelling of medical devices" was withdrawn on the 1st January

and replaced by ISO 15223-1:2012 "Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements"

In Europe that is of course....

mark walker 3rd April 2013 09:01 PM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Dear Bonebuilder . Sorry You should really get out more as 980 was with drawn and then Reinstated as i said in my previous mail.

Please back up your comments because im affraid im correct this time:)

mark walker 3rd April 2013 09:11 PM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

EU MDD, AIMDD, IVDD Harmonized Standards (EN980 & EN ISO 15223-1) Ooopppss!
Posted By leoeisner On @ In Uncategorized |
Comments Disabled

The EN 980 *Symbols for use in the labeling of medical devices* standard was mistakenly taken off of the EU Harmonized List of standards on the Jan 24, '13 release and EN ISO 15223-1 *Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements* was anticipated to be Harmonized but it wasn't Harmonized under the MDD, AIMDD, or IVDD.
The EU Commission has advised that the disappearance of EN 980 was a mistake and it is still Harmonized and will be corrected at the next release of the updated Harmonized Standards Listing, hopefully in the next few months. The EU Commission didn't Harmonize the EN ISO 15223-1 because they saw issues in relation to the Directives (MDD, AIMDD, & IVDD) and Annex Z's (e.g. Annex ZA, ZB, ZC) of the standard EN ISO 15223-1:2012.
Because the standard EN ISO 15223-1 wasn't Harmonized under this last round by the EU Commission CEN extended the date of withdrawal of EN ISO 15223-1:2012 from Jan 31, '13 to Jul 1, '15.
For access to the current list of Harmonized Standards, published Jan 24, '13, they are available thru our previous post **FDA & EU MDD / AIMDD / IVDD Updated Standards Lists**

[1]
.
Christine Ruther, an Eisner Safety Consultants Associate reminded us "The directives already allows the use of symbols from non-harmonized standards with the stipulation that the symbols and colours must be described in the documentation supplied with the device (e.g., MDD Annex I item 13.2). As most manufacturers define all symbols, regardless of origin, this gap in a harmonized standard for symbols should not be an issue.
In any event, manufacturers are expected to take a common sense approach to managing the situation. This will likely entail writing a short quality plan that acknowledges the situation and defines what actions will be taken. Actions might include waiting for the next update of harmonized standards to confirm which standards are harmonized, reviewing existing use of symbols to confirm compliance with EN ISO 15223-1 in anticipation of the change, or other actions." NOTE: It is not clear, at this point, if the EU Commission will Harmonize EN ISO 15223-1:2012 for the next publication of the List of Harmonized Standards for the MDD, AIMDD, & IVDD.
For Christine's part of this post we should also thank NSAI for forwarding information on this momentary vacuum.

Article printed from Eisner Safety Consultants:
http://www.eisnersafety.com

URL to article:
http://www.eisnersafety.com/eu-mdd-aimdd-ivdd-harmonizedstandards-en980-en-iso-15223-1-oooppps/

URLs in this post:
[1]

So ithink im owed a apology Mr Bonebuilder?

Bonebuilder

4th April 2013 04:45 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

bsi certainly think that it has been withdrawn, take a look, you'll find it at..

http://shop.bsigroup.com/ProductDeta...00000030122247

and I just got off the phone with their knowledge centre who say they are certain that 980 was withdrawn and replaced by 15223 in January. They are thou going to contact the council and come back to me to confirm.

Your right I should get out more but there it is! I'm clearly not as up to date in my reading of these postings as your good self...!

Any potential apology is therefore very much on hold until we have some impartial confirmation.

Regards

.

mark walker

5th April 2013 02:07 AM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

Sorry Bsi huh. Knowledge centre behind the times , so i still await a apology, or do i need to to talk You through the intent of Z annexes as well?

Happy to educate:bigwave:

Ronen E

22nd April 2013 11:14 PM

Re: Use of Symbols on Medical Device Labels - FDA Requirements

News flash from FDA:

> Quote:

The Food and Drug Administration (FDA) is proposing to revise medical device and biological product labeling regulations to explicitly allow for the inclusion of stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a standard developed by a nationally or internationally recognized standards development organization (SDO) (referred to in this document as a "standardized symbol'') and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices (or on a subset of medical devices), provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device. FDA is also proposing to revise prescription device labeling regulations to authorize the use of the symbol statement "Rx only'' on the labeling of prescription devices.

Read more: http://www.gpo.gov/fdsys/pkg/FR-2013...ce=govdelivery

If you are having problems Registering, Activating your Registration, or other problems, you can phone me in the US. I'm not here 24/7/365, but if I'm here I'll try to help.