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28 April 2004

Docket Management Branch  
[Docket No. 2003D-0367]  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, Rotville  
MD 20852

**Re. [Docket No. 2003D-0367] Draft Guidance for Industry on Providing  
Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications  
and Related Submissions**

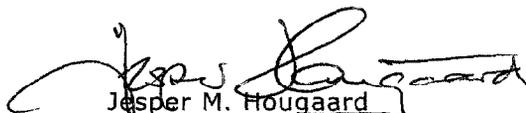
This submission is a formal petition to add the typeface Verdana to the list of recommended fonts as described in the above mentioned FDA draft guidance.

A justification (dated 2004-04-18) for proposing to use Verdana in electronic submissions is attached to this letter in two copies.

We look forward to feedback on this petition.

Please contact me directly at +45 72 26 23 03 or via e-mail if you have any questions regarding this submission.

Yours sincerely

  
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**03D-0367**

**C6**

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2004-04-18 10:00 AM -2 11:24

## SCOPE

This document is a formal petition to add the typeface Verdana (the font used in this document) to the list of recommended fonts as described in the FDA draft guidance from October 2003 "Guidance for Industry, Providing Regulatory Submissions in Electronic Format – General Considerations".

## THE FONT VERDANA

Verdana is a sans-serif typeface commissioned by the Typography Group at Microsoft Corporation, and designed by Matthew Carter (formerly of BitStream) specifically for use on low-resolution devices like monitors and laser printers. Hinting of Verdana was done by Monotype's hinting expert, Tom Rickner. [1], [2]

The Verdana typeface family with 4 styles – Verdana, Verdana Bold, Verdana Bold Italic and Verdana Italic - is continually being extended to support multilingual needs, and is currently available in version 2.41. [3]

Released in 1996, Verdana was bundled with subsequent versions of Microsoft's Windows operating system, as well as their Office and Internet Explorer software on both Windows and Mac OS. In addition, it was long available for free download from Microsoft's web site even by users of Linux and other Unix-like operating systems. As a result, it is now installed on most desktop computers (about 93 percent, according to one survey). The redistributable downloadable file is still available from third-party web sites. [1]

Verdana is extremely readable at small sizes, because of its lack of serifs, large x-height, wide proportions, loose letter-spacing, large counters, and emphasized distinctions between similarly-shaped characters, such as the lowercase i j l, the uppercase I J L and the numeral 1. Letter combinations such as "fi" "fl" and "ff" are designed so they clearly do not touch, as touching letters can create hard-to-read blobs on-screen. [2]

In on-screen typography it is important to keep the characters distinct from one another, and research has shown that wider letter spacing significantly aids reading from the screen. [3]

"Research shows no reliable differences in reading speed or user preferences between 10-point Times Roman, Georgia serif fonts, Helvetica, or Verdana sans serif fonts." [4]

All in all Verdana has been carefully drawn for maximum distinctiveness - an important characteristic of fonts designed for on-screen use. As a result, it is often chosen by web



designers attempting to cram large amounts of text into a small space, and has a high penetration of the market.

## **JUSTIFICATION**

There are two elements that may have an influence on the presentation and layout of the files generated via an EDMS – the operating system and the PDF-software.

### **OPERATING SYSTEM**

According to the latest market survey from Gartner Group (January 2004) the leading operating system is Microsoft Windows in various versions with more than 96% of all installations in new computers as it was the case in 2002. In 2003 78% of a total of 155 million units were sold with Windows XP installed. Probably due to the bundling of Microsoft's web browser, Internet Explorer now has a market share of almost 95% of all installations worldwide. [5]

Therefore we find it reasonable to base our conclusions on MS Windows – knowing that only a few percent of users worldwide are using other operating systems like Mac OS, Linux, UNIX etc.

Verdana is supported as a True Type font (TTF) in the following versions of MS Windows, MS Internet Explorer and MS Office Suites [3], [6], [7], [8], [9], [10]:

- Windows NT Option Pack, Windows 98, Windows 98 SE, Windows 2000, Windows XP
- Internet Explorer 4.0, Internet Explorer 4.01 SP1, Internet Explorer 4.01 SP2, Internet Explorer 5, Internet Explorer 6
- Microsoft Office 97 SBE SR2, Microsoft Office 2000, Microsoft Office XP

### **PDF SOFTWARE**

Using PDF files as part of the electronic documentation includes two disciplines – writing and reading. Typically, writing is handled automatically by the PDF Render Server, and reading is handled by Acrobat Reader – a worldwide distributed free software tool from Adobe. Verdana has been supported by the Adobe suite for the latest 3-4 versions, but to make absolutely sure that any PDF reader will present the content of the document as anticipated the PDF Render Server should be set to automatically embed all fonts used. Hence the PDF reader has no influence on the presentation and layout.

### **GUIDANCE FOR INDUSTRY**

In the latest draft guidance for Industry "Providing Regulatory Submissions in Electronic Format – General Considerations" (October 2003) it is stated in Section IV "What file formats should I use for electronic documents?" [11]:

- "We should be able to read all PDF files with Acrobat Reader version 4.0 and above..."



- "In some cases, font substitution can occur even when the fonts are available...on the reviewer's computer."
- "We cannot guarantee the availability of any one font. Therefore, you should embed all fonts you are using in the PDF files to ensure that those fonts will always be available to the reviewer."
- "However, font embedding does not solve the problems that occur when a reviewer tries to paste text from a PDF document into another software format. If the font is not available on the reviewer's computer, font substitution results even if the fonts are embedded. For this reason, we ask that you restrict the fonts used in documents to one of the following fonts listed in Table 1."

Points 1-3 concern the content presentation of PDF files in Acrobat Reader by embedding all fonts. Point 4 concerns the content presentation of text pasted from a PDF file into a word processor like MS Word, as part of the case handling of an application. As stated above, a true presentation of the pasted text (embedded Verdana) highly depends on the presence of Verdana in the current operating system.

The FDA initiative "eCTD Viewer System" (EVS) indicates that the basic software configuration provided by the FDA for an end user workstation includes Windows 98/NT/2000 and IE 5.5+. [12]

As the font Verdana has been supported since Windows 98, we are convinced that a pasted text will be presented as anticipated in any Windows application.

## REFERENCES

- [1] <http://en.wikipedia.org/wiki/Verdana>
- [2] <http://www.will-harris.com/verdana-georgia.htm>
- [3] <http://www.microsoft.com/typography/fonts/font.asp?FID=1&FNAME=Verdana>
- [4] <http://usability.gov/guidelines/fonts.html>
- [5] <http://futurezone.orf.at//futurezone.orf?read=detail&id=211494>
- [6] <http://support.microsoft.com/default.aspx?scid=kb;en-us;837463>
- [7] <http://www.adobe.com/support/techdocs/2f11e.htm>
- [8] <http://www.adobe.com/support/techdocs/2664e.htm>
- [9] <http://www.adobe.com/support/techdocs/2f412.htm>
- [10] <http://www.adobe.com/support/techdocs/2a39e.htm>
- [11] <http://www.fda.gov/cder/guidance/4156dft.pdf>
- [12] <http://www.fda.gov/cder/OIM/ESI/evsweb/server/other/EVSEnvironment.pdf>

