

From: <Saved by Windows Internet Explorer 8>
Subject: Electronic Code of Federal Regulations:
Date: Tue, 20 Mar 2012 12:02:12 -0400
MIME-Version: 1.0
Content-Type: multipart/related;
 type="text/html";
 boundary="----=_NextPart_000_0025_01CD0691.490F3390"
X-MimeOLE: Produced By Microsoft MimeOLE V6.00.2900.6157

This is a multi-part message in MIME format.

-----=_NextPart_000_0025_01CD0691.490F3390
Content-Type: text/html;
 charset="iso-8859-1"
Content-Transfer-Encoding: quoted-printable
Content-Location: mhtml:file:///C:/Documents and Settings/User/My Documents/
Downloads/21 CFR 1301.11 (1).mht

```
<!DOCTYPE HTML PUBLIC "-//W3C//DTD HTML 4.0 Transitional//EN">
<HTML><HEAD><TITLE>Electronic Code of Federal Regulations:</TITLE>
<META content=3D"text/html; charset=3Diso-8859-1" =
http-equiv=3DContent-Type><!-- InstanceBegin =
template=3D"/Templates/NEW_ecfr.dwt" codeOutsideHTMLIsLocked=3D"false" =
--><!-- #BeginEditable "doctitle" --><!-- #EndEditable -->
<META content=3D"text/html; charset=3Diso-8859-1" =
HTTP=3D'equiv=3D"Content-Type"'><LINK=20
rel=3Dstylesheet type=3Dtext/css=20
href=3D"http://ecfr.gpoaccess.gov/e/ecfr/styles/styles.css"><LINK =
rel=3Dstylesheet=20
type=3Dtext/css =
href=3D"http://ecfr.gpoaccess.gov/e/ecfr/styles/print.css"=20
media=3Dprint><!-- InstanceBeginEditable name=3D"head" --><!-- =
InstanceEndEditable -->
<STYLE>.white {
    PADDING-BOTTOM: 0px; MARGIN: 0px; PADDING-LEFT: 0px; PADDING-RIGHT: =
0px; COLOR: #ffffff; PADDING-TOP: 0px
}
</STYLE>

<SCRIPT>
<!-- Cloak code
function lepto(form)
{
var site=3Dform.dest.selectedIndex;

if (site>=3D1)

{ location=3Dform.dest.options[site].value; }

}
// Decloak -->
</SCRIPT>
<NOSCRIPT>
<META name=3DGENERATOR content=3D"MSHTML 8.00.6001.19190"></HEAD>
<BODY leftMargin=3D0 topMargin=3D0><A=20
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=3Decfr&sid=3D=
3abf8aa4ca34497a4b59fd9bcf96f249&rgn=3Ddiv8&view=3Dtext&node=3D=
21:9.0.1.1.2.0.2.4&idno=3D21#content"><IMG=20
border=3D0 alt=3D"Skip to content."=20
src=3D"mhtml:file:///C:/Documents and Settings/User/My =
Documents/Downloads/21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/spacer.gif"></A><A=20
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=3Decfr&sid=3D=
3abf8aa4ca34497a4b59fd9bcf96f249&rgn=3Ddiv8&view=3Dtext&node=3D=
```

21:9.0.1.1.2.0.2.4&idno=3D21#links"><IMG=20
border=3D0 alt=3D"Skip to side navigation."=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/spacer.gif">=20
Quick Navigation:=20

<A href=3D"http://www.gpoaccess.gov/topics/index.html" =
SELECTED>Resources by=20
Topic=20
Business =
&=20
Economy=20
<A =
href=3D"http://www.gpoaccess.gov/topics/education.html">Education=20
<A =
href=3D"http://www.gpoaccess.gov/topics/environment.html">Environment=
=20

Food & =
Drugs=20
Grants =
&=20
Awards=20
Health =
&=20
Safety=20
Military =
&=20
Security=20
Science =
&=20
Technology=20
Social=20
Programs=20
<A=20
=
href=3D"http://www.gpoaccess.gov/topics/transportation.html">Transportati=
on=20
</NOSCRIPT><!-- Beginning of top navigation. Do not modify. =
-->
<TABLE border=3D0 cellSpacing=3D0 cellPadding=3D0 width=3D"100%">
<TBODY>
<TR id=3Dtopnav><A=20
=
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=3Decfr&sid=3D=
3abf8aa4ca34497a4b59fd9bcf96f249&rgn=3Ddiv8&view=3Dtext&node=3D=
21:9.0.1.1.2.0.2.4&idno=3D21#content"><IMG=20
border=3D0 alt=3D"Skip to content."=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/spacer.gif"><A=20
=
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=3Decfr&sid=3D=
3abf8aa4ca34497a4b59fd9bcf96f249&rgn=3Ddiv8&view=3Dtext&node=3D=
21:9.0.1.1.2.0.2.4&idno=3D21#links"><IMG=20
border=3D0 alt=3D"Skip to side navigation."=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/spacer.gif"></TR>
<TR>
<TD id=3Dtopnav bgColor=3D#333399=20
background=3Dhttp://www.gpoaccess.gov/images/bg.gif>
<TABLE border=3D0 cellSpacing=3D0 cellPadding=3D0 width=3D700>

```

<TBODY>
<TR>
  <TD bgColor=3D#ffffff vAlign=3Dbottom rowSpan=3D2><A=20
    href=3D"http://www.gpoaccess.gov/"><IMG border=3D0=20
      alt=3D"GPO Access Home Page."=20
      src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/nav_01.gif"=20
      width=3D132 height=3D69></A></TD>
  <TD>
    <TABLE border=3D0 cellSpacing=3D0 cellPadding=3D2 =
width=3D568 height=3D38>
      <TBODY>
        <TR>
          <FORM name=3DquickNav>
            <TD bgColor=3D#ffffff height=3D3 vAlign=3Dbottom =
colSpan=3D2=20
              align=3Dleft><DIV align=3Dright><LABEL class=3Dwhite=20
for=3Dlabel_for_menu>Quick Navigation:</LABEL> <SELECT =
              style=3D"MARGIN: 0px; WIDTH: 145px; FONT-FAMILY: =
              Arial, Helvetica, sans-serif; FONT-SIZE: 9pt"=20
              id=3Dlabel_for_menu size=3D1 name=3DquickNavBar> =
<OPTION selected=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/index.html>Resources=20
              by Topic</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/business.html>Business=20
              & Economy</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/education.html>Education</OPTION>=
              =20
              <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/environment.html>Environment</OPT=
              ION>=20
              <OPTION =
              value=3Dhttp://www.gpoaccess.gov/topics/food.html>Food=20
              & Drugs</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/grants.html>Grants=20
              & Awards</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/health.html>Health=20
              & Safety</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/military.html>Military=20
              & Security</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/science.html>Science=20
              & Technology</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/programs.html>Social=20
              Programs</OPTION> <OPTION=20
              =
              value=3Dhttp://www.gpoaccess.gov/topics/transportation.html>Transportatio=
              n</OPTION></SELECT>=20
              <A title=3D"Jump to selected topic."=20
              =
              href=3D"javascript:location=3Ddocument.quickNav.quickNavBar.options[docum=
              ent.quickNav.quickNavBar.selectedIndex].value"><IMG=20
              border=3D0 hspace=3D0 alt=3D"Jump to selected topic."=20
              align=3DabsBottom=20

```

```
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/go.gif"=20
VALUE=3D""></A></DIV></TD></FORM><A name=3Dsearch></A>
<FORM name=3Dquery=20
action=3Dhttp://www.firstgov.gov/fgsearch/index.jsp>
<TD bgColor=3D#ffffff vAlign=3Dbottom width=3D70 =
align=3Dmiddle>
<DIV class=3Dsearch align=3Dright><LABEL =
for=3DxmW0>Site=20
Search:</LABEL> <BR><A=20
=
href=3D"http://www.gpoaccess.gov/advancedsearch.html"><SPAN=20
class=3Dsearch>advanced</SPAN></A></DIV></TD>
<TD bgColor=3D#ffffff vAlign=3Dbottom width=3D151 =
align=3Dleft>
<DIV align=3Dright><INPUT=20
style=3D"MARGIN: 0px; WIDTH: 110px; FONT-FAMILY: =
Arial, Helvetica, sans-serif; FONT-SIZE: 9pt"=20
id=3DxmW0 maxLength=3D50 align=3DabsMiddle name=3Dmw0 =
<INPUT=20
onkeypress=3Ddocument.query.submit();=20
onclick=3Ddocument.query.submit(); border=3D0 =
alt=3D"Submit Search"=20
align=3DabsMiddle=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/go.gif"=20
type=3Dimage> <INPUT value=3D0010 type=3Dhidden =
name=3Dadv> <INPUT=20
value=3D10 type=3Dhidden name=3Dnr> <INPUT value=3Dwww =
type=3Dhidden=20
name=3Ddb> <INPUT value=3D0 type=3Dhidden name=3Dfr> =
<INPUT value=3Dall=20
type=3Dhidden name=3Dmt0> <INPUT value=3Dshould =
type=3Dhidden=20
name=3Dms0> <INPUT value=3Ddetailed type=3Dhidden =
name=3Dde> <INPUT=20
value=3Ddomain type=3Dhidden name=3Dpl> <INPUT=20
value=3D"gpoaccess.gov, gpo.gov" type=3Dhidden =
name=3Ddomain>=20
</DIV></TD></FORM></TR></TBODY></TABLE></TD></TR>
<TR>
<TD><IMG border=3D0 alt=3D"Navigation Bar"=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://www.gpoaccess.gov/images/nav_03.gif"=20
width=3D568 height=3D44=20
useMap=3D#Map></TD></TR></TBODY></TABLE></TD></TR></TBODY></TABLE><MAP=20
name=3DMap><AREA href=3D"http://www.gpoaccess.gov/about/index.html" =
shape=3Dpoly=20
alt=3DAbout. coords=3D470,2,529,2,515,19,457,18><AREA=20
href=3D"http://www.gpoaccess.gov/help/index.html" shape=3Dpoly =
alt=3DHelp.=20
coords=3D407,2,466,2,452,19,394,18><AREA title=3D"A-Z Resource List."=20
href=3D"http://www.gpoaccess.gov/databases.html" shape=3Drect=20
alt=3D"A-Z Resource List." coords=3D1,23,121,43><AREA=20
title=3D"Locate a Federal Depository Library."=20
href=3D"http://www.gpoaccess.gov/libraries.html" shape=3Drect=20
alt=3D"Locate a Federal Depository Library." =
coords=3D124,24,332,43><AREA=20
title=3D"Buy Publications." href=3D"http://bookstore.gpo.gov/" =
shape=3Drect=20
alt=3D"Buy Publications." coords=3D335,22,444,43><AREA =
```

```
title=3DLegislative.=20
  href=3D"http://www.gpoaccess.gov/legislative.html" shape=3Drect =
alt=3DLegislative.=20
  coords=3D0,1,115,21><AREA title=3DExecutive.=20
  href=3D"http://www.gpoaccess.gov/executive.html" shape=3Drect =
alt=3DExecutive.=20
  coords=3D119,1,223,20><AREA title=3DJudicial.=20
  href=3D"http://www.gpoaccess.gov/judicial.html" shape=3Drect =
alt=3DJudicial.=20
  coords=3D227,1,310,21></MAP><!--End of top navigation. -->
<TABLE border=3D0 cellSpacing=3D0 cellPadding=3D0 width=3D700>
  <TBODY>
  <TR>
    <TD id=3Dleftnav bgColor=3D#333399 vAlign=3Dtop width=3D5><IMG =
alt=3D" " =20
      src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/e/ecfr/images/spacer.gif"=20
      width=3D5></TD>
    <TD id=3Dleftnav bgColor=3D#333399 vAlign=3Dtop width=3D135>
      <DIV align=3Dcenter><A name=3Dlinks></A><IMG=20
      alt=3D"National Archives and Records Administration logo."=20
      src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/e/ecfr/images/narablue.gif"=20
      width=3D120 height=3D122> </DIV><!-- #BeginLibraryItem =
"/library/leftnav.lbi" -->
      <TABLE border=3D0 cellSpacing=3D0 cellPadding=3D0 width=3D137 =
bgColor=3D#ffffff>
        <TBODY>
        <TR vAlign=3Dtop align=3Dleft>
          <TD height=3D12 colSpan=3D2>
            <DIV align=3Dcenter><IMG alt=3D"Database Features."=20
            src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/images/applicationfeatures.gif"=20
            width=3D137 height=3D16></DIV></TD></TR>
          <TR vAlign=3Dtop align=3Dleft>
            <TD height=3D5 colSpan=3D2><IMG alt=3D" " =20
            src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/images/spacer.gif"=20
            height=3D5></TD></TR>
          <TR vAlign=3Dtop align=3Dleft>
            <TD class=3Dside height=3D2 width=3D13>
              <DIV align=3Dcenter>=95</DIV></TD>
            <TD class=3Dside height=3D20><A=20
            =
            href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3D%2Findex.tpl">Browse</A></TD><=
/TR>
          <TR vAlign=3Dtop align=3Dleft>
            <TD class=3Dside height=3D2>
              <DIV align=3Dcenter>=95</DIV></TD>
            <TD class=3Dside height=3D20><A=20
            =
            href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;page=3Dsimple">Simple=20
            Search </A></TD></TR>
          <TR vAlign=3Dtop align=3Dleft>
            <TD class=3Dside height=3D19>
              <DIV align=3Dcenter>=95</DIV></TD>
            <TD class=3Dside height=3D19><FONT color=3D#000011=20
            face=3D"Arial, Helvetica, sans-serif">Advanced Search =
```

```
</FONT></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2>
      <DIV align=3Dcenter></DIV></TD>
    <TD class=3Dside height=3D20>* <A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;page=3Dboolean"=>20
      Boolean</A></TD></TR>
  <TR align=3Dmiddle>
    <TD height=3D20>&nbsp;</TD>
    <TD class=3Dside align=3Dleft>* <A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;page=3Dproximity"=>Proximity</A></TD>=
</TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2 align=3Dmiddle>=95</TD>
    <TD class=3Dside height=3D20><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;page=3Dhistory"=>Search=20
      History</A></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2 align=3Dmiddle>=95</TD>
    <TD class=3Dside height=3D20><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3Dsearch.tpl"=>Search=20
      Tips</A></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2>
      <DIV align=3Dcenter>=95</DIV></TD>
    <TD class=3Dside height=3D20><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3Dcorrectionspage.tpl"=>Correctio=
ns</A></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2>
      <DIV align=3Dcenter>=95</DIV></TD>
    <TD class=3Dside height=3D20>
      <P><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3Dupdate.tpl"=>Latest=20
      Updates</A></P></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2 align=3Dmiddle>=95</TD>
    <TD class=3Dside height=3D20><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3Dabout.tpl"=>User=20
      Info</A></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2 align=3Dmiddle>=95</TD>
    <TD class=3Dside height=3D20><A=20
      =
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=
b399355d56af19ea897&amp;c=3Decfr&amp;tpl=3Dfaq.tpl"=>FAQs</A></TD></TR>
  <TR vAlign=3Dtop align=3Dleft>
    <TD class=3Dside height=3D2>
      <DIV align=3Dcenter>=95</DIV></TD>
    <TD class=3Dside height=3D20><A=20
```

=
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=b399355d56af19ea897&c=3Decfr&tpl=3D%2Fagencylist.tpl">Agency=20
List</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D35><A=20
=
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=b399355d56af19ea897&c=3Decfr&tpl=3Dibr.tpl">Incorporation=20
by Reference</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D20><A=20
=
href=3D"http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=3D7ee9467c7aec0=b399355d56af19ea897&c=3Decfr&tpl=3D%2Findex.tpl">e-CFR=20
Main Page</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD height=3D2 colSpan=3D2><IMG alt=3D" "=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/images/bottom.gif"=20
width=3D137 height=3D16></TD></TR></TBODY></TABLE>
<TABLE border=3D0 cellSpacing=3D0 cellPadding=3D0 width=3D137 =
bgColor=3D#ffffff>
<TBODY>
<TR vAlign=3Dtop align=3Dleft>
<TD height=3D12 colSpan=3D2>
<DIV align=3Dcenter><IMG alt=3D"Related Resources"=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/e/ecfr/images/related.gif"=20
width=3D137 height=3D16></DIV></TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD height=3D5 colSpan=3D2><IMG alt=3D" "=20
src=3D"mhtml:file://C:\Documents and Settings\User\My =
Documents\Downloads\21 CFR 1301.11 =
(1).mht!http://ecfr.gpoaccess.gov/e/ecfr/images/spacer.gif"=20
height=3D5></TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2 width=3D13>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D35><A=20
href=3D"http://www.gpoaccess.gov/cfr/index.html">Code of =
Federal=20
Regulations</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D20><A=20
href=3D"http://www.gpoaccess.gov/fr/index.html">Federal=20
Register</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D35><A=20
href=3D"http://www.gpoaccess.gov/lsa/index.html">List of=20
CFR
Sections Affected</TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>

```
<TD class=3Dside height=3D20 width=3D132><A=20
=
href=3D"http://www.regulations.gov/">Regulations.gov</A></TD></TR>
<TR vAlign=3Dtop align=3Dleft>
<TD class=3Dside height=3D2>
<DIV align=3Dcenter>=95</DIV></TD>
<TD class=3Dside height=3D20 width=3D132><A=20
href=3D"http://www.gpoaccess.gov/ua/index.html">Unified=20
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imports, or
exports any controlled substance or who proposes to engage in the
manufacture, distribution, dispensing, importation or exportation
of any
controlled substance shall obtain a registration unless exempted
by law or
pursuant to 1301.22 through 1301.26. Except as provided in
paragraph (b)
of this section, only persons actually engaged in such activities
are
required to obtain a registration; related or affiliated persons
who are
not engaged in such activities are not required to be registered.
(For
example, a stockholder or parent corporation of a corporation
manufacturing controlled substances is not required to obtain a
registration.)

(b) As provided in sections 303(f) and 401(h) of the Act (21
U.S.C.
823(f) and 841(h)), it is unlawful for any person who falls within
the
definition of online pharmacy (as set forth in section
102(52)
Act (21 U.S.C. 802(52)) and 1300.04(h) of this chapter) to
deliver,
distribute, or dispense a controlled substance by means of the
Internet if
such person is not validly registered with a modification of such
registration authorizing such activity (unless such person is
exempt from
such modified registration requirement under the Act or this
chapter). The
Act further provides that the Administrator may only issue such
modification of registration to a person who is registered as a
pharmacy
under section 303(f) of the Act (21 U.S.C. 823(f)). Accordingly,
any
pharmacy registered pursuant to 1301.13 of this part that falls
within
the definition of an online pharmacy and proposes to dispense
controlled
substances by means of the Internet must obtain a modification of
its
registration authorizing such activity following the submission of
an
application in accordance with 1301.19 of this part. This
requirement
does not apply to a registered pharmacy that does not fall within
the
definition of an online pharmacy set forth in 1300.04(h). Under
the Act,
persons other than registered pharmacies are not eligible to
obtain such a
modification of registration but remain liable under section
401(h) of the
Act (21 U.S.C. 841(h)) if they deliver, distribute, or dispense a
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[74 FR 15621, Apr. 6, 2009]

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WJAGf3K6PGzgzS2k74GRtoJTFft3bnVxf5sqp/BuhBLzhtRIlyoL4IAFIABii6JJ9XRgD3bfQBDC
yG/FqXVkt/aANnb1BgAcE3Zoj3bPA/JOUUQhP3Zlz3aMnNaKtMoCERlpD3dx97yJkAtiXw5ux+QN
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Content-Transfer-Encoding: base64
Content-Location: http://www.gpoaccess.gov/images/bg.gif

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3rz7D4biSjBmiabqyrbuC8cJQNf2jef6zvF+DwwKh8Si8YhMKpFmpvMJrcLIgar1is1qt9yu9ws0
i8fksvmMTqvX7Lb7DY/L5+UCADS=

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Content-Type: text/css;
charset="iso-8859-1"
Content-Transfer-Encoding: quoted-printable
Content-Location: http://ecfr.gpoaccess.gov/e/ecfr/styles/styles.css

```
.td {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 12px
}
.tr {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 12px
}
.h1 {
    LINE-HEIGHT: 18pt; FONT-FAMILY: Arial, Helvetica, sans-serif; =
    FONT-SIZE: 16px; FONT-WEIGHT: bold; Arial:=20
}
.h2 {
    PADDING-BOTTOM: 0px; LINE-HEIGHT: normal; FONT-STYLE: normal; =
    PADDING-LEFT: 0px; PADDING-RIGHT: 0px; FONT-FAMILY: Arial, Helvetica, =
    sans-serif; MARGIN-BOTTOM: 0px; COLOR: #000000; FONT-SIZE: 14px; =
    FONT-WEIGHT: bold; PADDING-TOP: 0px
}
.h3 {
    LINE-HEIGHT: normal; FONT-STYLE: normal; FONT-FAMILY: Arial, Helvetica, =
    sans-serif; MARGIN-BOTTOM: 0px; FONT-SIZE: 12px; FONT-WEIGHT: bold
}
.caption {
    LINE-HEIGHT: normal; FONT-STYLE: normal; FONT-FAMILY: Arial, Helvetica, =
    sans-serif; MARGIN-BOTTOM: 0px; FONT-SIZE: 12px; FONT-WEIGHT: bold
}
```

```

}
.footer {
    TEXT-ALIGN: center; FONT-FAMILY: Arial, Helvetica, sans-serif; =
BACKGROUND-POSITION: center 50%; FONT-SIZE: 10px
}
.top {
    TEXT-ALIGN: right; FONT-FAMILY: Arial, Helvetica, sans-serif; =
FONT-SIZE: 10px
}
.tablespacing {
    PADDING-BOTTOM: 5px; PADDING-LEFT: 5px; PADDING-RIGHT: 5px; =
PADDING-TOP: 10px
}
.fontsmall {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 11px
}
.navigation {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 10px
}
.invisiblelink {
    FONT-FAMILY: Arial, Helvetica, sans-serif; COLOR: #ffffff; FONT-SIZE: =
10px; TEXT-DECORATION: none
}
A.menubar:link {
    COLOR: blue
}
A.menubar:visited {
    COLOR: purple
}
A.menubar:hover {
    COLOR: #cc3333
}
A.menubar:active {
    COLOR: purple
}
.toplogo {
    LINE-HEIGHT: normal; FONT-STYLE: normal; FONT-FAMILY: Arial, Helvetica, =
sans-serif; MARGIN-BOTTOM: 0px; FONT-SIZE: 14px; FONT-WEIGHT: bold
}
.search {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 10px
}
.side {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 12px
}
.subparagraph {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 12px; TOP: -5px; =
FONT-WEIGHT: normal
}
.head {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 18px; =
FONT-WEIGHT: bolder
}
.recentupdateslink {
    TEXT-ALIGN: left; FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: =
12px; FONT-WEIGHT: bolder
}
.updatetitle {
    TEXT-ALIGN: left; TEXT-INDENT: 5pt; FONT-FAMILY: Arial, Helvetica, =
sans-serif; COLOR: #ff0000; FONT-SIZE: 14px; FONT-WEIGHT: bold
}
.updatebodytest {
    TEXT-ALIGN: left; FONT-VARIANT: normal; FONT-STYLE: normal; =
FONT-FAMILY: Arial, Helvetica, sans-serif; BACKGROUND-POSITION: left =

```

```

50%; FONT-SIZE: 12px; FONT-WEIGHT: normal
}
.updatebold {
    TEXT-ALIGN: left; FONT-STYLE: normal; FONT-FAMILY: Arial, Helvetica, =
sans-serif; BACKGROUND-POSITION: left 50%; FONT-SIZE: 12px; FONT-WEIGHT: =
bold
}
.body {
    BACKGROUND-COLOR: #ffffff; FONT-FAMILY: Arial, sans-serif; COLOR: =
#000000
}
.a {
    TEXT-DECORATION: underline
}
.a:link {
    BACKGROUND-COLOR: #ffffff; COLOR: blue
}
.a:visited {
    BACKGROUND-COLOR: #ffffff; COLOR: red
}
.a:active {
    BACKGROUND-COLOR: #ffffff; COLOR: #ff0000
}
.p {
    TEXT-ALIGN: center; WIDTH: 474px; BACKGROUND-REPEAT: no-repeat; =
FONT-FAMILY: Arial, sans-serif; FONT-WEIGHT: normal
}
.title {
    TEXT-ALIGN: left; FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: =
20px; FONT-WEIGHT: bold
}
.subtitle {
    TEXT-ALIGN: left; FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: =
14px; FONT-WEIGHT: bold
}
.mainheader {
    FONT-SIZE: 130%; FONT-WEIGHT: bold
}
.chapter {
    TEXT-ALIGN: left; FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: =
16px; FONT-WEIGHT: bold
}
.subchapter {
    TEXT-ALIGN: left; FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: =
14px; FONT-WEIGHT: bold
}
.part {
    FONT-SIZE: 100%; FONT-WEIGHT: bold
}
.subpart {
    BACKGROUND-COLOR: #ffffff; COLOR: blue; FONT-SIZE: 90%
}
.nopart {
    BACKGROUND-COLOR: #ffffff; COLOR: green
}
.reserved {
    BACKGROUND-COLOR: #ffffff; COLOR: red
}
.menu {
    FONT-FAMILY: Arial, Helvetica, sans-serif; FONT-SIZE: 12px
}
.hilite {
    COLOR: #cc0000; FONT-WEIGHT: bold
}

```

```
.gpotbl_hang {
    TEXT-INDENT: -2em
}
.gpotbl_table {
    BORDER-COLLAPSE: collapse; EMPTY-CELLS: show; PADDING-TOP: 0.5em
}
.gpotbl_div {
    BORDER-BOTTOM: black 2px solid; BORDER-LEFT: black 2px solid; =
BORDER-TOP: black 2px solid; BORDER-RIGHT: black 2px solid; space-after: =
0.25em
}
.gpotbl_title {
    TEXT-ALIGN: center; PADDING-BOTTOM: 0.5em; FONT-WEIGHT: bold
}
.gpotbl_description {
    TEXT-ALIGN: center
}
.gpotbl_cell {
    BORDER-BOTTOM: black 1px solid; BORDER-LEFT: black 1px solid; =
VERTICAL-ALIGN: top; BORDER-TOP: black 1px solid; BORDER-RIGHT: black =
1px solid
}
.gpotbl_colhed {
    BORDER-BOTTOM: black 1px solid; BORDER-LEFT: black 1px solid; =
VERTICAL-ALIGN: bottom; BORDER-TOP: black 1px solid; BORDER-RIGHT: black =
1px solid
}
.gpotbl_note {
=09
}
```

```
-----=_NextPart_000_0025_01CD0691.490F3390
Content-Type: text/css;
    charset="iso-8859-1"
Content-Transfer-Encoding: 7bit
Content-Location: http://ecfr.gpoaccess.gov/e/ecfr/styles/print.css
```

```
#topnav {
    DISPLAY: none
}
#leftnav {
    DISPLAY: none
}
.tablespacing {
    PADDING-LEFT: 0px
}
```

```
-----=_NextPart_000_0025_01CD0691.490F3390--
```