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FIS is available
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seven days a
week. It
provides general
entry to a
series of
systems which
enable
electronic
submissions to
the Food and
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Administration

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FDA launches
food safety plan
builder |
Morning Ag Clips
The Food Safety
Plan Builder
(FSPB) is a free
software
application,
developed by FDA
that businesses
can download

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from the FDA's website to guide them, step-by-step, through the creation of a food safety plan, as required by FSMA.

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FSPB Application

User Guide Page

| 2 2

Introducing Food

Safety Plan

Builder Figure

1: Food Safety

Plan Builder

Introduction The

U.S. Food and

Drug

Administration's

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(FDA) Food
Safety Plan
Builder (FSPB)
is a user-
friendly, stand-
alone
application
designed to
assist
owners/operators
of a food
facility in the

Food and Drug

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Note that the
links in the
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Guides database
go directly to
the first page
of the
Medication Guide
within the drug
label. Please
check the number
of Medication
Guide pages

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before printing.

FDA launches
Food Defense
Plan Builder 2.0
to simplify IA

...

The user is
taken through a
series of
sections (tabs)
in the
application that
prompt the user

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to answer
questions and/or
fill in
information
specific to
their business
and facility.

Once all the
tabs have been
completed, the
file may be
saved or
printed, and the
firm will have a

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food safety plan
to use in its
operations and
to provide when
the FDA conducts
an inspection.

FDA Releases
Food Safety Plan
Software
AccessData's
targeted,
forensically
sound

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collection,
preservation, FDA
hold, processing
and data
assessment tools
lower costs and
reduce risks.

Risk &
Compliance Find
information
risks across
enterprise
endpoints and
destroy them

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with powerful,
proven
enterprise
search, forensic
collection and
analysis to
locate data and
assess
compliance.

CVM eCATS Step-
by-Step
Instructions for
Industry

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Corporate

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East Timpanogos
Circle Building
H, Floor 2,
Suite 2300 Orem,
UT 84097

Medication
Guides | FDA
FIS was created,
in part, in
response to the

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Bioterrorism Act of 2002, which gave high priority to improved information management to help protect the food supply. The Act requires that FDA develop two systems: one to support the registration of

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facilities that
manufacture,
process, pack,
or hold food
products
intended for
consumption in
the United
States and one
to receive prior
notice before
...

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...

FDA also released a user guide with more detailed information. Perhaps not surprising in light of the subject matter, the user guide

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includes a
lengthy legal
disclaimer
putting users on
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makes no
warranties of
any kind and
admits of no
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any damages, and
that “[r]esponsi
bility for the
interpretation

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and use of the
[FSPB] and of
the accompanying
documentation
lies ...

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accessdata fda,
it is very easy

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then, since
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is a free
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application,
developed by
FDA, that
businesses can
download from

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the FDA's
website to guide
them, step-by-
step, through
the creation of
a ...

Frequently Asked
Questions FAQs
Abbott i-STAT
In the user
guide, FDA also
is careful to
note that

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although the content of the Food Defense Plan Builder v. 2.0 is consistent with its existing regulations and guidance, use of the tool does not constitute FDA approval of a food defence plan or

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guarantee
compliance with
FDA's
requirements.

Food First Blog
| FDA Launches
Food Safety Plan
Builder to ...

The user is
taken through a
series of
sections (tabs)
in the

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application that prompt the user to answer questions and/or fill in information specific to their business and facility.

Once all the tabs have been completed, the file may be saved or

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printed, and the firm will have a food safety plan to use in its operations and to provide when the FDA conducts an inspection.

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The U.S. Food
and Drug

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Administration's
(FDA) Food
Safety Plan
Builder (FSPB)
is a tool
designed to
assist
owners/operators
of food
facilities with
the development
of food safety
plans that are

...

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Forensic Toolkit

(FTK) version

7.1.0 |

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Frequently Asked
Questions

(FAQs), Abbott i-
STAT Updated as
of 04/29/2020 .

FAQ #

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them, step-by-
step, through
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a ...

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Silver Spring,
MD 20993
www.fda.gov June
28, 2019 Dexcom,
Inc. Emily Chung
Senior
Specialist,

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Regulatory
Affairs 6310 Fda

Sequence Dr. San
Diego, CA 92121

Re: K191450

Trade/Device

Name: Dexcom G6

Glucose Program

Continuous

Glucose

Monitoring

System

Food Safety Plan

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User Guide Page

| 1 1 Food

Safety Plan

Builder v.1.3

Legal Disclaimer

The Food Safety

Plan Builder

(FSPB) v.1.3 is

a user-friendly

tool designed to

help owners and

operators of a

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food
establishment
with the
development of a
food safety plan
that is specific
to their
facilities.

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