CBI’s Mobile Medical Apps Summit

The Evolution of a Dosing Calculator from a Drug-Related Promotional Item to a Medical Device

Jill Charbonneau
Director, RA-Ad/Prom, Product Launch & Labeling
Disclaimer

The views and opinions expressed herein are my own and are not the official views of my company.

Every organization is unique and encouraged to consult with their own experts and internal teams before adopting or changing a practice or policy.
Topic of Discussion

The intersection of device regulations and drug promotion regulations when an App such as a dosing calculator is developed can be confusing! Questions that need to be asked and answered when developing, reviewing and approving an App to stay compliant and still competitive include:

- Is my App a device?
- Does it require a 510(k)? PMA? Device listing?
- Is my App a promotional item?
- Does it require a 2253 submission?
Mobile Medical App Categories

1. **Regulated Medical Device**
   - Defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is...
   - Intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.” *

2. **Enforcement Discretion**
   - Including General Wellness Low Risk Products

3. **Not a Regulated Medical Device**

* Section 201(h) of the FD&C Act
Apps Regulated as Medical Devices

Follow Medical Device Regulations!

Accessories to a medical device
- Apps that connect to a medical device for purposes of controlling the device, active patient monitoring, or analyzing medical device data

Functionalities similar to currently regulated medical devices
- Transforms mobile platform into a regulated medical device by using attachments, display screens or sensors
- App uses a hardware attachment or interface to a monitoring system

Clinical Decision Support Software
- App performs patient-specific analysis
- App interprets data from another medical device
- Provides patient-specific diagnosis or treatment recommendations

Adapted from: Mobile Medical Applications Guidance for Industry and FDA Staff Issued Feb 9, 2015
http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf
Regulated – Now What?

Talk to your Device Regulatory Folks!

General Controls apply such as:

- Investigational Device Exemption requirements
- Premarket Submission 510(k) or PMA
  - For Class I devices exempt from 510(k), the submission of a 510(k) and marketing clearance from FDA is not required
- Establishment Registration and Device Listing,
- Device Labeling requirements,
- Quality System Regulation and Good Manufacturing Practices,
- Medical Device Reporting requirements
- Recalls, Corrections and Removals
Enforcement Discretion

Still need to follow Quality System Regulations

1. Patient motivators
2. Patient day-timers
3. Access to contextually relevant information
4. Apps to help patients communicate with HCPs (videoconferencing, documenting or transmitting photos)
5. Simple professional calculators
6. Connections to EHR’s
7. Apps that meet the definition of Med Device Data Systems when used as a secondary display, not for primary diagnosis, monitoring or treatment decisions

Adapted from 2015 FDA Advertising & Promotion Conference: Mobile Medical Device Apps Presentation: FDA Regulatory Landscape by Bradley Merrill Thompson, Epstein Becker & Green

General Wellness Products: Enforcement Discretion

Apps, and more Apps

“CDRH does not intend to examine low risk general wellness products to determine whether they are devices”

General Wellness Product Criteria

| Intended ONLY for General Wellness Use | Presents a very low risk to users’ safety |

“General wellness products may include exercise equipment, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the two factors above.”

Is your App a General Wellness Product?

Ask these questions

Only General Wellness Claims?

Does not present risk to user’s safety?

Chronic Condition with well understood lifestyle role?

General Wellness Product

Claim to help reduce risk of or living with chronic condition?

Claim Relating to Disease or Medical Condition?

Not Regulated

Examples

1. Electronic copies of medical textbooks
2. Educational tools
3. Facilitate patient access to information
4. Business operations in healthcare settings (accounting, billing)
5. Generic aid (e.g. magnifying glass)

Adapted from: Mobile Medical Applications Guidance for Industry and FDA Staff Issued Feb 9.2015
http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf
DOSE/ DOSING CALCULATORS
## Calculators Regulated as Devices

<table>
<thead>
<tr>
<th>Regulation Number</th>
<th>Device</th>
<th>Device Class</th>
<th>Regulation Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>[862.2100]</td>
<td>Digital Image Storage And Communications Non-Diagnostic Laboratory Information System</td>
<td>1</td>
<td>Calculator/data processing module for clinical use.</td>
<td></td>
</tr>
<tr>
<td>[862.2100]</td>
<td>Calculator/Data Processing Module For Clinical Use</td>
<td>1</td>
<td>Calculator/data processing module for clinical use.</td>
<td></td>
</tr>
<tr>
<td>[868.1900]</td>
<td>Calculator Pulmonary Function Interpreter (Diagnostic)</td>
<td>2</td>
<td>Diagnostic pulmonary-function interpretation calculator.</td>
<td></td>
</tr>
</tbody>
</table>
K121542: Picis Weight Based Dose Converter  
K141321: GlucoStabilizer® Insulin Dosing Calculator |
| [892.5050]        | Software Product intended to compute a radiotherapy dose volume         | 2            | Medical charged-particle radiation therapy system                                       | K150848: Model 1218028 Dose Calculator |

[Link](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=calculator&ProductCode=&DeviceClass=&ThirdParty=&Panel=&RegulationNumber=&GMPExempt=&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10) downloaded 9/8/15
### Example of Calculator Classified/Regulated as a Medical Device

<table>
<thead>
<tr>
<th>PART 868 -- ANESTHESIOLOGY DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart B--Diagnostic Devices</td>
</tr>
</tbody>
</table>

#### TITLE 21--FOOD AND DRUGS

**CHAPTER I--FOOD AND DRUG ADMINISTRATION**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**SUBCHAPTER H--MEDICAL DEVICES**
**PART 868 -- ANESTHESIOLOGY DEVICES**
Subpart B--Diagnostic Devices

Sec. 868.1890 Predictive pulmonary-function value *calculator*.

(a) **Identification.** A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) **Classification.** Class II (performance standards).

Dosing Calculator Apps

Does App communicate calculated dose to infusion pump?

Does App use patient specific parameters and calculate dosage for treatment planning software?

Is Dosing Calculator functioning as a simple basic calculator?

Is Dosing Calculator functioning as a spreadsheet/slide rule?

Is it or isn’t it a REGULATED Medical Device?

Is App providing convenient electronic access to general information? (e.g. conversion of lbs to kg)
Dosing Calculator Apps

My App communicates calculated dose to infusion pump or other drug delivery system

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Audience Response Results

My App communicates calculated dose to infusion pump or other drug delivery system

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Dosing Calculator Apps

My App uses patient specific parameters and calculates dosage for treatment planning software

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Audience Response Results

My App uses patient specific parameters and calculates dosage for treatment planning software

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Dosing Calculator Apps

My Dosing Calculator App functions as a simple basic calculator

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Audience Response Results

My Dosing Calculator App functions as a simple basic calculator

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Dosing Calculator Apps

My Dosing Calculator App is an electronic version of the old spreadsheet/slide rule Dosing Card

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Audience Response Results

My Dosing Calculator App is an electronic version of the old spreadsheet/slide rule Dosing Card

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe

What if....?
Would you change your answer if “Slide Rule” Calculator considered a) simple basic calculator, or b) facilitates patient access to information?

Would you change your answer if item is for a specific drug?
My App provides convenient electronic access to general information (e.g. conversion of lbs to kg)

Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
My App provides convenient electronic access to general information (e.g. conversion of lbs to kg)
Is it a REGULATED Medical Device?

1 = Yes, Regulated
2 = Enforcement Discretion
3 = Not Regulated
4 = It Depends/Maybe
Dosing Calculator Apps

- **Does App communicate calculated dose to infusion pump?**
- **Does App use patient specific parameters and calculate dosage for treatment planning software?**
- **Is Dosing Calculator functioning as a simple basic calculator?**
- **Is Dosing Calculator functioning as a spreadsheet/sliding rule?**
- **Is App providing convenient electronic access to general information? (e.g., conversion of lbs to kg)**
What about.....?

Consider this:

- Does it work?
  - If it doesn’t work, does anyone get hurt?

- Is it accurate?

- Who’s checking?
  - Verified?
  - Validated?
  -Confirmed?
What about…..?

Consider this:

What functionality is claimed in the App description?

- Beware of description of functionality – “Intended Use”

- Example from Recent Enforcement letter:
  - “FDA has determined that your website promotes these products for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)].
  - The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.” (Biomedic Labs, LLC 10/28/15)
Dosing Calculator Apps Out There Now

MOST DOWNLOADED IN MEDICAL CALCULATOR

- MedCalc (medical calculator) $1.99
- Medical Calculator $0.99
- Calculate (Medical Calculator) by FREE
- Mediquations Medical Calculator $4.09
- MediMath Medical Calculator $4.09
- AppsMedical 6-in-1: drugs & $0.99
- MedSolve Medical Calculator $0.99

![Insulin Dose Calculator](image)

Number of Points Your Blood Glucose Will Be Reduced per Insulin Unit:

Answer: 55 units

[Marathon Pharmaceuticals, LLC]
DOSE/ DOSING CALCULATORS AS PROMOTIONAL ITEMS
Remember when...

Paper, paper, paper

- **Dosing cards with sliding insert**
  - Also known as a Dosing Slide Chart
  - "*Designed to aid medical professionals in administration of drug therapies. Also known as dosing calculators, dosage charts, dosage slide rules.*"

- **Favorite promotional item giveaway, distributed by Sales Reps**

* http://www.datalizer.com/resources/glossary.html
Remember when...

Paper, paper, paper

- Considered *purview* of Rx Drug Ad/Promo Only

- Biggest concern was accuracy of “spreadsheet” insert and how do I get a PI in there?

- Submitted to FDA (2253)

* [http://www.datalizer.com/resources/glossary.html](http://www.datalizer.com/resources/glossary.html)
Dosing Calculator Apps: NOW - the Promotional Requirements

**IS IT BRANDED FOR SPECIFIC DRUG? If YES:**

- Truthful, not misleading
- Supported by substantial evidence
- Balanced: Important Safety Information (ISI)/Important Risk Information (IRI)
- Provision of full Prescribing Information [aka Package Insert] (PI)

**Submission Required**

Regulated as Drug Promotional Labeling, so talk to your Drug Ad/Prom Regulatory Folks!
## 2253 Form

<table>
<thead>
<tr>
<th>Form Approved: CMB No. 2110-2001, Expiration Date: December 31, 2017; see FDA Statement on last page</th>
</tr>
</thead>
</table>

### DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

### TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

**NOTE:** Form FDA 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81).

#### 4. Proprietary Name
- **Product Code No.:**

#### 5. Established Name
- **Established Name:**
- **Product Code No.:**

#### 6. Package Insert Date and ID Number
- **Latest time printed (inserting):**
- **License No. (Biologics):**

#### 2. Advertising / Promotional Labeling Materials
- **Material Type (use FDA codes):**
  - **Material ID Code (use FDA codes):**
  - **Material Description:**

To delete a row, click the “Delete Row” button for that row (or press the enter key). If you've tabbed into this button, you cannot delete the last row: Add New Row

#### 1. Comments

### 3. Applicant's or Agent's Return Address
- **Address 1 (Street address, P.O. Box, company name, etc.):**
- **Address 2 (Apartment, suite, unit, building, floor, etc.):**
- **City:**
- **State/Province/Region:**
- **ZIP or Postal Code:**

### 10. Responsible Official or Agent
- **Telephone Number (include area code):**
- **Fax Number (include area code):**
- **Email Address:**

### 11. Typed Name and Title of Responsible Official or Agent

### 12. Signature of Responsible Official or Agent

### 13. Date

### 14. For CBER Products Only (Check one)
- **Draft**
- **Final**

**FORM FDA 2253 (12/14)**

**PREVIOUS EDITION IS OBSOLETE**

**Page 1 of 2**
What about...?
Ask your marketing team:

- How is it being “rolled out”?
- How is it described?
- Will there be “Introduction”/link on product website?
- Any other ancillary materials?
- Is it open to public access?
What about...?

Ask your marketing team:

- Are you able to review it as pdfs of screenshots as well as in a test environment?

- Consider adding additional reviewers to normal Ad/Prom review team: IT, Device RA, Device QA

- Are you able to optimize PI and IRI for mobile?

- Will you have pdfs of screenshots and descriptions for FDA 2253 submission?
What does the future hold?
Technology keeps moving

“Ford is working with SDI Health and pollen.com to create an App that would monitor pollen conditions to keep allergy and asthma sufferers aware of pollen forecasts and index levels.

Ford and Medtronic are also collaborating on a medical device App that would connect Medtronic’s glucose-monitoring devices to the Sync system wirelessly via Bluetooth. In turn, Sync would display glucose levels to drivers on the vehicle’s LCD screen and provide a warning if the values fell below safe levels. Sync could also use the WellDoc DiabetesManager service to compare current readings to those taken earlier in the day.”

What does the future hold?

FDA gets in on the “App” Act

“The Orange Book Express mobile app reflects our commitment to keep up with the latest technologies, developing effective means for the public to access important and useful information about generic drugs. The app also makes the Orange Book available to a wider audience than ever before - supporting users who may not always have convenient access to a computer or wired Internet connection.”

Source: http://www.fda.gov/Drugs/default.htm
Sources for some of the graphic images contained herein

- osceApp
- mathfest.wikispaces.com
- lastwordblog.blogspot.com
- En.Wikipedia
- http://www.datalizer.com/resources/glossary.html
- http://appcrawlr.com/app/search?category=&price=&q=infusion+calculator&_src=xRemo...&action=search&&controller=app&device=%5Biphone%5D&_rv=1