Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists

April 30, 2020
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Dean and Professor
Loma Linda University School of Pharmacy
President, APhA

Host and Moderator
Today’s Focus:

Overview from FDA representatives on compounding, including how it relates to drug shortages
Guest Speakers

FDA – Center for Drug Evaluation and Research (CDER)

Gail Bormel, R.Ph., J.D.
Associate Director for Compounding (Acting)
Office of Compliance

Gabrielle Cosel, M.Sc.
Acting Senior Advisor for Compounding
Office of Compliance

Ian Deveau, Ph.D.
Division Director (Acting)
Office of Manufacturing Quality, Office of Compliance
Daniel Zlott, PharmD, BCOP
Vice President
Professional Education Resources
American Pharmacists Association

Subject Matter Expert: Q&A
Michael Baxter  
Senior Director, Regulatory Policy  
American Pharmacists Association  

Subject Matter Expert: Q&A
Format for Today’s Webinar

1:00 pm: Introductions – Michael Hogue
1:05 pm: Discussion with FDA representatives Gail Bormel, Gabrielle Cosel Ian Deveau, from the Center for Drug Evaluation and Research (CDER) – Michael Hogue
Presentation: COVID-19 Human Drug Compounding Update
Gail Bormel
1:25 pm: Open Forum: A Minute for Your Thoughts – Michael Hogue
1:50 pm: Wrap Up: Review of APhA’s Ongoing Activities and What’s Coming
Discussion with FDA

Overview from FDA representatives on compounding, including how it relates to drug shortages
COVID-19:
Human Drug Compounding Update

Compounding Program
FDA’s CDER Office of Compliance

Ian Deveau, Ph.D.
Gabey Cosel, M.Sc.
Gail Bormel, R.Ph., J.D.
COVID-19 Compounding Guidances


- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry 4/20/2020

- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency 4/16/2020

- Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency 4/22/2020

- Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Update 4/15/2020
Personal Protective Equipment

Conditions include:

• Employs mitigation strategies to reduce the risk of product contamination
• Keeps record when compounding is performed without standard PPE
• Keeps record when there are changes in the sterilization approach
• Documents mitigation strategies
• Guidance is intended only for pharmacy compounders that are not registered as outsourcing facilities
COVID-19 Compounding by Pharmacies and Federal Facilities

Temporary enforcement discretion related to:
• “Essentially a copy” provision
• Prescription requirement

Conditions include:
• Appendix A Drugs
• Hospital attempts to obtain FDA-approved drugs or drugs from Outsourcing Facilities
• Pharmacy notifies board of pharmacy and board does not object (state in which pharmacy is located and if different, state in which hospital located)
• Mark order with hospital and COVID-19; request patients receiving drugs within one month
• Beyond use date limited
COVID-19 Compounding By Outsourcing Facilities

Temporary enforcement discretion related to:

• “Essentially a copy” provision
• 503B bulks list
• Stability studies

Conditions include:

• Appendix A
• Hospital attempts to obtain FDA-approved drugs
• Beyond use date considerations
Repackaging and Combining of Propofol During COVID-19

- Addresses repackaging or combining propofol drug products from the same and different manufacturers
- Products prepared in the same column are given a BUD of not more than 12 hours
- Products in column A or column B are not combined with a propofol drug product in any column other than its own.
- Products in columns C, D, or E are combined with a BUD of not more than 4 hours
- Hospital attempts to obtain FDA-approved drugs
Appendix A: Propofol Drug Products

To repack or combine propofol drug products as described in the circumstances described in item 3 of this guidance, FDA provides the following table. Products that are included in the same column of this table may be prepared and given a BUD of not more than 12 hours consistent with the circumstances described in item 3.b. of this guidance because the preservatives/antioxidants in the DESCRIPTION section of the approved labeling match. To fall under the circumstances described in this guidance, propofol drug products in column A or column B are not to be combined with a propofol drug product in any column other than its own. Propofol drug products in columns C, D, or E may be combined with a BUD of not more than 4 hours consistent with the circumstances described in item 3.c. of this guidance.

<table>
<thead>
<tr>
<th>A: Manufacturer/application number</th>
<th>B: Manufacturer</th>
<th>C: Manufacturer</th>
<th>D: Manufacturer</th>
<th>E: Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresenius Kabi (NDA 019627)</td>
<td>Sagent Pharmaceuticals (ANDA 075102)</td>
<td>Hospira, Inc. (ANDA 077908)</td>
<td>Dr. Reddy’s Laboratories (ANDA 205067)</td>
<td>Watson Laboratories, Inc. (ANDA 205307)</td>
</tr>
<tr>
<td>NDCs of applicant: 63323-269-XX; 65219-800-XX</td>
<td>25021-608-XX</td>
<td>0409-4699-XX</td>
<td>43598-269-XX; 43598-548-XX; 43598-549-XX</td>
<td>0591-2136-XX</td>
</tr>
<tr>
<td>Labeler/NDC</td>
<td>HF Acquisition Co LLC, DBA HealthFirst: 51662-1471-1</td>
<td>HF Acquisition Co LLC, DBA HealthFirst: 51662-1293-1 (20 mL)</td>
<td>HF Acquisition Co LLC, DBA HealthFirst: (100 mL) 51662-1470-1</td>
<td></td>
</tr>
</tbody>
</table>

17 For instance, a drug in column A is not to be mixed with a drug in columns B-E; a drug in column B is not to be combined with a drug in column A or columns C-E.

18 National Drug Code. The first 8 digits in the NDC code of the product used should match that NDC code in the table. XX refers to the package code. This number can vary.
Alcohol-Based Hand Sanitizer Products

One condition includes the hand sanitizer is compounded according to the following formula consistent with WHO recommendations:

a. Alcohol (ethanol, denatured) (formulated to 80%, volume/volume (v/v)) in an aqueous solution; or Isopropyl Alcohol (formulated to 75%, v/v) in an aqueous solution.,
b. Glycerin (glycerol) (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The compounder does not add other active or inactive ingredients, such as ingredients to improve the smell or taste due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.
Questions

• Hand Sanitizer Guidance: COVID-19-Hand-Sanitizers@fda.hhs.gov

• Propofol Guidance: CDER-OPQ-Inquiries@fda.hhs.gov

• Other Guidances: Compounding@fda.hhs.gov
Polling Question

I have been able to address some of the drug shortages in my practice with compounded products:

A. Yes
B. No
C. Not applicable to my position
Open Forum Ground Rules

• Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.

• Individuals whose submissions are selected will be asked by the moderator to state the comment or question for the audience. The line for the individual will be unmuted to read their comment or question.

• To maximize the number of questions/comments addressed, a **60-second time limit** will be in effect for everyone to state their question or comment.

• We will try to get to as many comments and questions as possible. We have created a new forum for COVID-19 discussions where further discussion post-webinar. Information on participating in this forum will be provided at the end of the open forum.
Open Forum Discussion: A Minute for Your Thoughts
Comments, Questions, Feedback
Review of APhA’s Ongoing Activities and What’s Coming
NEW Episodes – APhA’s 15 on COVID-19

An education series designed to help you sort COVID-19 fact from fiction. Each episode is 15-20 minutes and provides CPE.

Episode 11: Viral Properties and Remdesivir Updates

Episode 12: Zinc
Pharmacists & COVID-19 Testing

Diagnostic Testing

- We need to build a collection network to meet this new laboratory capacity.
- Today, I am signing an Executive Order allowing independent pharmacists to conduct diagnostic coronavirus tests.
Tell Congress Pharmacists Can Help Fight COVID-19 & Influenza

Congress is currently crafting new emergency legislation to address the COVID-19 pandemic. Please contact your federal legislators immediately and ask them to allow pharmacists to test Medicare patients for COVID-19 and influenza.

You can personalize the message by editing the content to share a relevant personal experience related to patient care. Legislators value real life examples of pharmacists helping patients. Remember to be polite and include your name and the city of your residence or pharmacy practice.

GO TO: actioncenter.pharmacist.com
Check out **NEW practice resources**

- Engaging the Pharmacist Workforce to Address the COVID-19 Crisis
- COVID-19: Providing Outpatient Pharmacy Services in a Field Surge Hospital: A Checklist of Considerations Shared by the Pharmacy Team at UNC Health
- Vaccines in Development for COVID-19
COVID-19 Clinical Links by Practice Area

Check out the key clinical links that may be helpful for your clinical practice

• Pharmacists Clinical Care of Patients
• Managing Your Pharmacy
• Testing
• Compounding
• Pharmacist Well-Being and Resilience
• Vaccinations
• Frequently Asked Questions
Post on ENGAGE
Pharmacy’s Response to COVID-19

POST your questions
SHARE your lessons learned
SUPPORT your colleagues
ACCESS the latest information

What types of drug shortages are you experiencing?
What are your biggest compounding challenges?
Join Us

Same day, Same time, Same Place

• Weekly webinar #7 will be on Thursday, May 7th, from 1-2 pm ET
• The webinar recording and slides will be available within 24 hours

https://www.pharmacist.com/coronavirus/resources-training