

Delivering on Quality

A Manufacturer's Perspective
February 23, 2021



Agenda



Hand Sanitizer Production The Perrigo Story

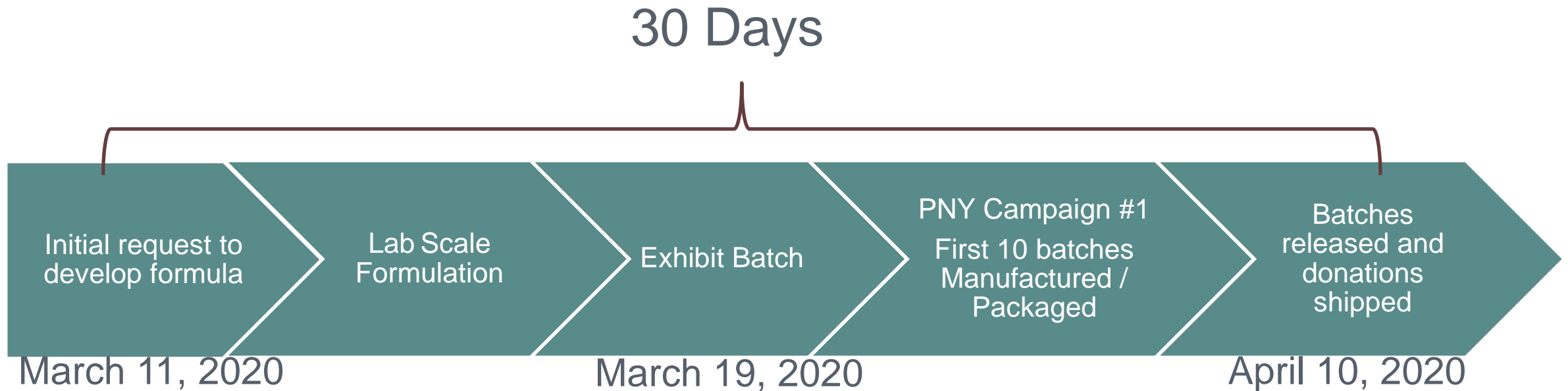
- Timeline
- Development/Formulation
- Analytical Methods
- Packaging
- Stability Strategy
- Exhibit Batch
- Commercial Production
- Site Transfer
- Alcohol ID Guidance
- Donations



The Perrigo Story



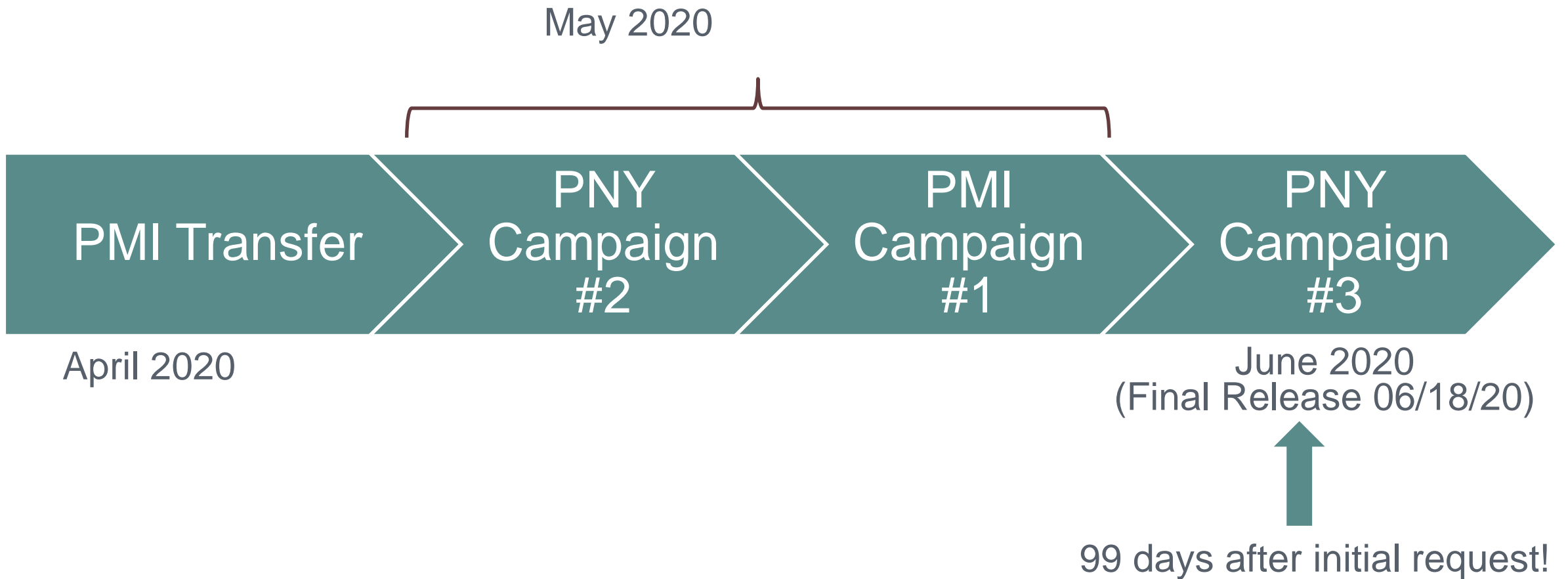
From Conception to first Donations



Timeline continued



Continued Production for Donation



99 days after initial request!

FDA Guidance Formula vs New Product Development

- ▶ Option 1: FDA Guidance “Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency”
 - EtOH/IPA, Glycerin, Hydrogen Peroxide, Purified Water
 - Pros: formula given in guidance, no pre-market stability, no expiration dating concerns.
 - Cons: Formulation is a liquid (product difficult to use & to control dosing), No existing internally approved H₂O₂ material.

- ▶ Option 2: Develop a gel-based formula
 - Pro: Product easy to use, familiar to users (most commercially available personal hand sanitizer products are gel-based), use of existing RMs.
 - Con: Requires formulation work, pre-market stability.

- ▶ Perrigo opted to develop a gel-based formula.

Perrigo New York Formulation R&D

- ▶ A partially developed formula from the 1990's was used as a starting point.
- ▶ Suitable Raw Materials selected from materials already approved at PNY.
 - 1 RM was inactive, however previously used/approved
- ▶ RM orders were expedited
- ▶ 10 lab scale batches were made to further develop formulation.
- ▶ Batch size limited by safety concerns with flammability of EtOH.
- ▶ Process optimization – batch card updates were occurring until day of exhibit batch.
 - Alcohol concentration was key, calculation based on 190 proof RM
 - Screen added to ensure clarity of product

Perrigo Michigan Analytical R&D

- ▶ Analytical method for EtOH was developed
 - Biggest obstacles
 - Time
 - First product samples received < week prior to exhibit batch
 - Robustness and consistency of methodology due to gel formula components
- ▶ Expedited documentation for method/specifications prior to testing exhibit batch
- ▶ Expedited EI assessment
- ▶ Analytical Method Validation Plan
- ▶ Exhibit Batch and Stability Testing Plan

Packaging Development



- ▶ Use existing components
 - 2 oz Bottles & Caps
- ▶ 6 bottle/cap configurations packaged for exhibit batch
 - 3 bottles, 2 caps (w/ and w/out induction seal)
 - All evaluated for stability
- ▶ 1 bottle chosen, both caps for commercialization
- ▶ Additional external 8-12 oz pump bottle options evaluated

Perrigo New York Exhibit Batch



- ▶ Manufactured March 19, 2020
- ▶ Exhibit Batch size: 300 kg
- ▶ Cleaning Validation Waived
 - Toxicity, Solubility, API volatility, Comparable RM use in other formulations, etc.
- ▶ Packaged into 6 configurations
- ▶ Method transfer not yet complete
 - Batches tested at PMI AR&D lab
- ▶ All configurations placed on Stability

Expedited Approach

- ▶ Stress stability (50°C/75% RH)
- ▶ Formal stability (40°C/75% RH & 25°C/60% RH)
- ▶ Stability Trend extrapolation based on available data from completed stations
- ▶ Shelf life extended as more data was available (3 month → 6 month → 16 month)
- ▶ Bulk Stability
 - Tested concurrently, 2 months
 - Forward thinking – donation batches prepared directly prior to filling

Campaign #1

- ▶ Scale-up to 1500 kg batch size (~25k bottles)
- ▶ Initial campaign of 10 batches – manufactured 03/26-04/07
- ▶ First 3 were Validation batches - Both cap options challenged during validation
- ▶ At-risk pending stability assessment / shelf life
 - 1st stability assessment / shelf life justification complete 04/09/20 – assigned 3-month expiry
- ▶ Method transfers to PNY from PMI
- ▶ Testing of commercial batches performed at both locations to expedite release
- ▶ April 10: 1st donations shipped & employee distribution (6 of 10 batches released)
- ▶ Full campaign released by 04/13/20

2 additional campaigns of 10 batches each

- ▶ Campaign 2
 - 6-Month Expiry
 - Manufactured 04/30-05/07
 - Released 05/11-05/15

- ▶ Campaign 3
 - 16-Month Expiry
 - Manufactured 06/04-06/12
 - Released 06/16-06/18



Formula Site Transfer

- ▶ ~8 Lab scale batches to optimize process for PMI equipment
- ▶ 1 Full Scale R&D Batch
 - Scale up to 4,210 kg (~70k bottles)
- ▶ RM Transfer
 - Shortage of denatured alcohol / No equivalent RM at PMI
 - Denatured existing EtOH RM w/ IPA
 - Use of equivalent RMs approved at PMI
 - Expedite approval and documentation for using PNY RMs at PMI
 - Materials transferred from PNY for batch execution
- ▶ Challenges based on moving to a liquid filling line
 - Diameter of Piping
 - Evaluation of Pump
- ▶ Stability Waiver Justification

1 Campaign for Donations

- ▶ Initial campaign of 2 batches (manufactured 05/06 & 05/12)
 - Limited based on donation need in areas
- ▶ 6-month Shelf Life
- ▶ Overcame ongoing challenges due to novelty of gel-based formula for the site
- ▶ Method transfers to PMI QC
- ▶ Testing of batches performed in both AR&D & QC to expedite release
- ▶ Released on 05/21 & 06/11

Special Considerations for Alcohol



Policy for Testing of Alcohol and Isopropyl Alcohol for Methanol

- ▶ FDA Guidance – January 2021
 - ID testing for Methanol, NMT 200ppm
 - ID on each container received
 - Drums vs. Tankers have significantly different lab burdens
 - FP method should distinguish between Ethanol (or IPA) and Methanol
- ▶ USP monograph for Alcohol updated to include this ID test
- ▶ USP monograph for Isopropyl alcohol not yet updated, however FDA guidance specifies to apply the 200 ppm limit for this as well.
- ▶ FDA guidance is for Ethanol/Isopropyl alcohol – not only in relation to hand sanitizer.

Hand Sanitizer Donations



By June approximately 1 Million Units were donated!

- 1st Responders
- Employees
- Hospitals
- Shelters
- Food Pantries
- Charitable Organizations

Celebrating Success



To commemorate this momentous achievement, Perrigo distributed framed awards:

- **Over 225 Individual Contributors**
- **Across Many Departments**
- **From NY to MI to Ireland**



COVID-19 EMERGENCY RESPONSE

**PROJECT INITIATION:
MARCH 11, 2020**

**FIRST DONATION/SHIPMENT:
APRIL 10, 2020**

Perrigo®

Questions



Empowering a healthy tomorrow