Ohio MHAS
Promoting wellness and recovery

Update (November 7, 2016)

It has recently come to our attention that additional items sold by Teleflex Medical are also subject to recall. These items are not stocked by Ohio Pharmacy Services, but may be in use within your organization. Linked below is the full list of recalled products from Teleflex Medical. Additional items also subject to recall include a number of syringe/atomizers combinations, due to the same concern that the recalled devices may not appropriately create the mist required for proper absorption of medications. To see the full recall list issued by Teleflex Medical, click here.

DATE: November 7, 2016

FROM: Tracy Plouck, Director
Ohio Department of Mental Health & Addiction Services

SUBJECT: Nasal Atomizer Recall (Item #MAD300)

The Ohio Department of Mental Health and Addiction Services (Ohio MHAS) has been made aware of a product recall issued by Teleflex Medical, the makers of the MAD300 nasal atomizer used to administer naloxone in the event of an opiate overdose. Such devices are included in the Project DAWN kits, which may have been distributed to your organization, or you may have purchased this device directly from a pharmacy or other distributor. The product recall was issued for 32 lot numbers of the Teleflex Medical MAD300 nasal atomizer.

This recall does not impact the medication itself, but rather the nasal atomizer, which is used to administer the drug. The recall was issued after it was discovered that faulty atomizers shoot a stream of naloxone into patients' noses rather than producing a mist, potentially making the overdose reversal drug less effective.

If you currently have a supply of naloxone, do not discard the medication. Many nasal atomizers are not subject to this recall. However, if your organization utilizes these atomizers and/or possesses Project DAWN kits, we are asking that you check the lot numbers on all atomizers you have in supply.

The following lot numbers are listed in the product recall. For help in locating the atomizer lot number please see the attached examples.

160108	160231	160440	160708
160117	160300	160500	160718
160126	160313	160518	160728
160145	160327	160602	160800
160146	160400	160611	160804
160200	160409	160621	160814

160219	160422	160631	160816
160225	160432	160701	160823

If it is discovered that nasal atomizers in your possession are impacted by the recall, please return the product to your naloxone supplier.

-more-

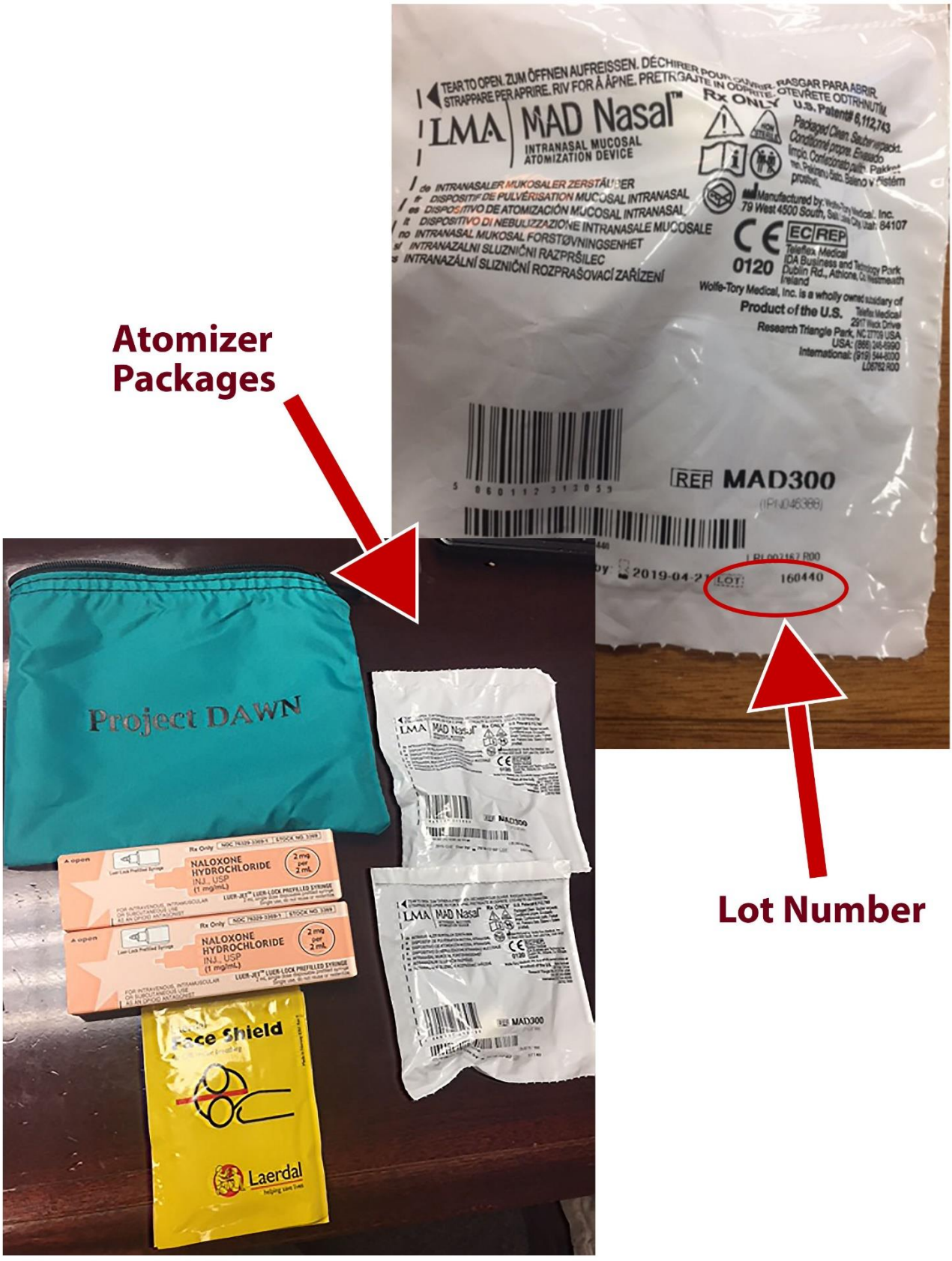
The recall contains the following statement:

> "Teleflex Medical is recalling these products as they may not deliver a fully atomized plume of medication. Teleflex Medical has received complaints that the affected lots produced a straight stream instead of an atomized spray. The failure of the device to deliver an atomized plume may impair the effectiveness of the medication with which it is used. This can lead to serious injury or death in certain emergency situations, such as where the device is used in an off-label manner for needle-free delivery of drugs for reversal of life threatening narcotic overdose, reversal of life threatening hypoglycemia, or treatment of epileptic seizures."

At this time Teleflex Medical has not established a date when they will be releasing new product. Alternative forms of naloxone may be available, including Narcan NS™. This product contains two intranasal plunger devices that deliver 4mg of naloxone per dose. We encourage you to visit www.pharmacy.ohio.gov\stopoverdose to view the list of pharmacies that may have this product in stock. It is recommended that you call the pharmacy in advance to confirm availability.

If you have any questions about this recall, please call our toll-free hotline: 1-844-364-4063

###


Atomizer Packages
Lot Number
LMA MAD Nasal™
INTRANASAL MUCOSAL ATOMIZATION DEVICE
Rx ONLY
REF MAD300
LOT 160440
Project DAWN
NALOXONE HYDROCHLORIDE INJ., USP (1 mg/mL)
Face Shield
Laerdal