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USP presentation on Medication Errors relating to the labeling and packaging of various drug products in low-density polyethylene plastic vials

FDA Drug Safety and Risk Management Advisory Committee
May 5, 2004

Eric Sheinin, Ph.D.
Vice President, Information & Standards Development
United States Pharmacopeia

12601 Twinbrook Parkway
Rockville, MD 20852

301-881-0666
www.usp.org

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My name is Eric Sheinin and I am here today to represent the United States Pharmacopeia. I am the Vice President for Information and Standards Development at USP.

The USP is a non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. These standards are developed by a unique process of public involvement and are accepted worldwide. USP is a not-for-profit organization that achieves its goals through the contributions of volunteers representing pharmacy, medicine, and other health care professions, as well as science, academia, the U.S. government, the pharmaceutical industry, and consumer organizations. In addition to standards development, USP's other public health programs focus on promoting optimal health care delivery.

The members of the Council of Experts and its Expert Committees are USP's scientific decision makers and standards-setting body. Council members are elected by USP's membership on the basis of their knowledge and expertise and serve five-year terms. The 2000-2005 Council

of Experts comprises 62 nationally and internationally recognized scientists, academicians, and clinicians. Each member chairs a committee of distinguished experts.

One of those committees is the USP Safe Medication Use Expert Committee, which is comprised of 18 members representing pharmacy, nursing, and medicine and includes an FDA liaison, Carol Holquist. CPT Jerry Phillips, the former, Associate Director for Medication Error Prevention, FDA Office of Drug Safety is a member of this committee of experts.

For more than 30 years, USP has promoted the importance of collecting and sharing experiential data from health care professionals. In the last decade, particular emphasis has been focused on medication error reporting and prevention as a way for USP to positively affect the public health. The data collected from two programs, the USP-ISMP Medication Errors Reporting (MER) Program and MEDMARX[SM] are reviewed and analyzed by USP staff and USP's Expert Committee on Safe Medication Use.

In October of 2002, USP sent a letter to the Chief of CDER's Compendial Operations staff, Yana Mille, to inform her, on behalf of the USP Safe Medication Use Expert Committee, of the continuing concerns of the Committee and of health care practitioners regarding the inability to identify drug products in low density polyethylene plastic ampuls and vials, and the resultant medication errors.

Plastic ampul packaging is frequently used for respiratory therapy drugs. The ampuls often do not bear labels but are labeled by debossing/embossing the actual plastic container. This debossing/embossing is described by health care practitioners reporting to the USP-ISMP Medication Errors Reporting Program and MEDMARX as being unreadable, causing difficulty in identifying the product within. Because this packaging is now being used not only for respiratory therapy drugs, but also for injectable and oral solutions, it is even more important that labels be easily readable and that the products be readily distinguishable one from another.

USP provided the Compendial Operations staff, the Dockets Branch, and the Office of Drug Safety, with more than 42 specific case studies where medication errors were

involved with these products. We also submitted copies of the actual product containers involved in the medication errors reported through the USP Programs.

In addition to providing comment on the concerns expressed to USP by health care practitioners, the USP Safe Medication Use Expert Committee unanimously voted to encourage FDA to establish an alternate method of labeling for the various drug products in the plastic vials being discussed today, so that these products are clearly identifiable and will reduce the numerous medication errors occurring. The Committee also suggested that the FDA cease approval of products in these containers because their use continues to be the subject of numerous medication errors.

From April 20, 2002 through January 31, 2004 an additional 26 reports of actual and potential medication errors have been received through USP's medication errors reporting program regarding the similarity in the labeling of products in low density polyethylene vials. The problem with these products continues and USP and the USP Safe Medication Use Expert Committee recommends that FDA take the necessary actions to improve the labeling of Low Density Polyethylene ampuls and vials.

Thank you for your attention and consideration.

Eric Sheinin

Vice President, Information and Standards Development

United States Pharmacopeia

12601 Twinbrook Parkway

Rockville, Maryland 20852

301-816-8103

es@usp.org

MEDERR DDP REPORT

Access Number: 054958
8/13/2003 5:44:47 PM **erf**

Date Received at USP: 5/1/2002 **Date of Report** 4/18/2002

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	Unit-dose
Manufacturer:	Ivax	**NDC Number:**	00172-6405-44
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	Unit-dose
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054958

8/13/2003 5:44:47 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

The manufacturers might want to put a paper label on each vial, similar to what Dey Labs does on their Albuterol product (it is clear what drug it is, the label is blue, and the printed material is easy to read).

REMARKS

Problem:

We just wanted to bring to your attention, that the packaging of Ipratropium Bromide unit-dose vials (by Roxane Laboratories; NDC [National Drug Code] number 0054-8402-11) and packaging of Albuterol Sulfate unit-dose vials (by Zenith Goldline; NDC number 0172-6405-44) are dangerously similar - both are clear plastic vials, with letters imprinted on them. The shape is similar, and it is very hard to read what is written on the vial, thus creating a potential for confusion and wrong drug being dispensed.

Roxane Laboratories letter to the reporter dated August 5, 2002: Your comments regarding Roxane Laboratories' packaging will be forwarded to its Product Management Committee for review.

MEDERR DDP REPORT

Access Number: 055017
8/13/2003 5:44:47 PM **erf**

Date Received at USP: 5/15/2002 **Date of Report** 4/15/2002

Product Name: Ipratropium Bromide	**Container Type:** Plastic ampul
Generic Name(s): Ipratropium Bromide	**Container Size:**
Manufacturer: Roxane Lab Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength:	**Sample Available:** No

Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:**
Manufacturer: Sepracor Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength:	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055017

8/13/2003 5:44:48 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The manager of cardio-pulmonary noticed that when Xopenex (Levalbuterol by Sepracor) unit-dose inhalation solution is removed from the foil wrapper the unit is almost indistinguishable from Ipratropium Bromide unit-dose (by Roxane). They both are in semi-clear plastic with the name in raised plastic but not really distinguishable without really looking in good lighting. Our respiratory technicians sometimes carry these around out of the foil. We are not aware of a mix-up yet, but it seems only a matter of time.

Roxane Laboratories reply to the reporter dated August 29, 2002: Your comments regarding our vial will be forwarded to our Product Management Committee for review.

Sepracor Inc. reply to the reporter dated September 27, 2002: The LDPE (low-density Polyethylene) dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the three dose strengths, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this require FDA (Food and Drug Administration) approval before being marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 055044
8/13/2003 5:44:48 PM

erf

Date Received at USP: 5/20/2002 **Date of Report** 5/20/2002

Product Name: Albuterol Sulfate	**Container Type:** Plastic ampul
Generic Name(s): Albuterol Sulfate	**Container Size:** 3 mL
Manufacturer: Alpharma USPD, Inc.	**NDC Number:** 0472-0831-23
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 2.5 mg/3 mL	**Sample Available:** No
Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:** 3 mL
Manufacturer: Sepracor Inc.	**NDC Number:** 63204-0512-24
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.63 mg	**Sample Available:** No
Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:**
Manufacturer: Sepracor Inc.	**NDC Number:** 63402-0513-24
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 1.25 mg	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 055044

8/13/2003 5:44:48 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Changing packaging for easily distinguishable.

REMARKS

Problem:

Look-alike medications noted. No error occurred. Paramedic noticed similarity. The potential for error was discovered while on usual rounds.

Sepracor reply to the reporter dated December 4, 2002: Sepracor appreciates receiving this information so that we are aware of the problems and have the opportunity to give them proper attention.

MEDERR DDP REPORT

Access Number: 055139
8/13/2003 5:44:48 PM **erf**

Date Received at USP: 6/11/2002 **Date of Report** 6/10/2002

Product Name: Albuterol Sulfate	**Container Type:** Plastic Ampul
Generic Name(s): Albuterol Sulfate	**Container Size:** 3 mL
Manufacturer: Alpharma USPD, Inc.	**NDC Number:** 00472-0831-23
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.083%	**Sample Available:** No
Product Name: Atrovent	**Container Type:** Plastic Ampul
Generic Name(s): Ipratropium Bromide	**Container Size:** 2.5 mL
Manufacturer: Boehringer Ingelheim	**NDC Number:** 00597-0080-62
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.02%	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? Respiratory therapist

Describe Outcome: No adverse outcome was known to occur to the patient.

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Respiratory therapist

When and how was the error discovered? The error was discovered when a dose of Atrovent nebulization was being administered to a patient. The patient was given a dose of Albuterol instead of Atrovent. When the storage bins were examined more closely, the Albuterol bullets were mixed with the Atrovent bullets (and vice versa) in the storage containers.

Where did the error occur? Hospital

Was another practitioner involved in the error? Yes

If yes, what type of practitioner? Respiratory therapist

Was patient counseling provided? Yes

If yes, before or after error was discovered? After

Number of occurrences:

MEDERR DDP REPORT

Access Number: 055139

8/13/2003 5:44:48 PM **erf**

Patient information that might be relevant:

Unknown

Reporter's recommendations or policies to prevent future similar errors:

To avoid further error like this from happening in the future, we recommend that the labeling for the two products be made more legible (that is: separate paper label on bullet versus engraved labeling), or that some other labeling technique be used that more clearly differentiate these products.

REMARKS

Problem:

A respiratory therapist, who was administering a nebulization treatment to a patient, noticed that what she thought was an Atrovent nebulizer was actually an Albuterol nebulizer. When the therapist looked at the stocks of medication, it was also apparent that the Albuterol and Atrovent bullets were intermixed in each of the bins. The package size, shape, and labeling are similar for the two products. Also, the name of the product is difficult to see, as it is engraved in the clear plastic.

Roxane Laboratories reply to the reporter dated September 12, 2002:
Your comments regarding our vial will be forwarded to Roxane Laboratories' Product Management Committee for review.

MEDERR DDP REPORT

Access Number: 055181
8/13/2003 5:44:48 PM **erf**

Date Received at USP: 7/3/2002 **Date of Report** 7/3/2002

Product Name: Albuterol Sulfate	**Container Type:** Plastic ampul
Generic Name(s): Albuterol Sulfate	**Container Size:**
Manufacturer: Various	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 2.5 mg/3 mL	**Sample Available:** No
Product Name: Smartamp Heparin Lock Flush	**Container Type:** Plastic ampul
Generic Name(s): Heparin Sodium	**Container Size:**
Manufacturer: American Pharmaceutical Partners	**NDC Number:** 63323-929-05
Labeler:	**Adm. Route:** Injection
Dosage Form: Injectable	**Lot Number(s):**
Strength: 10 u/mL	**Sample Available:** No
Product Name: Sodium Chloride	**Container Type:** Plastic ampul
Generic Name(s): Sodium Chloride	**Container Size:**
Manufacturer: Various	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 3%	**Sample Available:** No
Product Name: Ipratropium Bromide	**Container Type:** Plastic ampul
Generic Name(s): Ipratropium Bromide	**Container Size:**
Manufacturer: Various	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.5 mg/2.5 mL	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

MEDERR DDP REPORT

Access Number: 055181

8/13/2003 5:44:48 PM **erf**

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The ampuls look very similar and may be mistaken for a nebulizing solution.

MEDERR DDP REPORT

Access Number: 055185
8/13/2003 5:44:48 PM **erf**

Date Received at USP: 7/9/2002 **Date of Report** 7/3/2002

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0831-60
Labeler:	Automatic Liquid Packaging	**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	2.5 mg/3 mL	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:	Automatic Liquid Packaging	**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055185

8/13/2003 5:44:48 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

This is a dangerous problem and really needs to be addressed promptly. We've decided to switch to Dey's Albuterol, which is well labeled, until the labeling of Alpharma's brand is improved. The FDA (Food and Drug Administration), manufacturers, and buying groups need to make it a priority to eliminate the practice of embossing clear letters on clear ampules. Medication errors are inevitable in this situation.

REMARKS

Problem:

Respiratory therapists noted that Alpharma's Albuterol Sulfate inhalant solution 0.083 % (in plastic ampuls) looks nearly identical to Sepracor's Xopenex 0.63 mg plastic ampules. Both are clear plastic with the lettering embossed in clear letters. It's almost impossible to read the lettering. The therapists are quite concerned that this raises the risk of a medication error. Both brands of ampules need to be labeled much more clearly. Error was discovered presumably when the therapist went to give a dose.

Sepracor reply to the reporter dated December 4, 2002: Sepracor appreciates receiving this information so that we are aware of the problems and have the opportunity to give them proper attention.

MEDERR DDP REPORT

Access Number: 055157
8/13/2003 5:44:48 PM **erf**

Date Received at USP: 8/7/2002 **Date of Report** 8/2/2002

Product Name:	Heparin Lock Flush	**Container Type:**	Plastic ampul
Generic Name(s):	Heparin Sodium	**Container Size:**	5 mL
Manufacturer:	American Pharmaceutical Partners	**NDC Number:**	
Labeler:		**Adm. Route:**	Injection
Dosage Form:	Injectable	**Lot Number(s):**	
Strength:	10 units/mL	**Sample Available:**	No

Product Name:	Tobi	**Container Type:**	Plastic ampul
Generic Name(s):	Tobramycin	**Container Size:**	5 mL
Manufacturer:	Chiron Corporation	**NDC Number:**	53905-0065-01
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	60 mg/mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055157

8/13/2003 5:44:48 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

An anonymous reporter asks if there is an awareness that APP (American Pharmaceutical Partners, Inc.) is marketing a Heparin 10 units/mL-5 mL plastic container. One of their representatives was showing it to the reporter last week. The reporter showed the representative, who was also surprised, all of the respiratory medications and the poor labeling. The clincher is that their Heparin product is almost identical to the Tobramycin for inhalation product Tobi. We told them we could not purchase their product for this reason alone. The potential for error was discovered during review and comparison of product labeling.

MEDERR DDP REPORT

Access Number: 055158
8/13/2003 5:44:48 PM **erf**

Date Received at USP: 8/7/2002 **Date of Report** 8/2/2002

Product Name: Smartamp Heparin Lock Flush	**Container Type:** Plastic ampul
Generic Name(s): Heparin Sodium	**Container Size:**
Manufacturer: American Pharmaceutical Partners	**NDC Number:**
Labeler:	**Adm. Route:** Injection
Dosage Form: Injectable	**Lot Number(s):**
Strength:	**Sample Available:** No
Product Name: Sodium Chloride	**Container Type:** Plastic ampul
Generic Name(s): Sodium Chloride	**Container Size:**
Manufacturer: N/I	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength:	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055158

8/13/2003 5:44:48 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

I run a professional organization for health-system pharmacists, and several of my members have brought to my attention a concern for potential errors when using the new American Pharmaceutical Partners (APP) Heparin Lock Flush Solution in the SmartAmp delivery system. The ampul looks very similar to Sodium Chloride for inhalation as well as other inhalation ampules. There is a concern that the injection will be confused for the inhalation and vice versa. Concerns were mentioned to several APP representatives however to no avail. The potential for error was discovered during review of product labeling.

MEDERR DDP REPORT

Access Number: 055190

8/13/2003 5:44:48 PM **erf**

Date Received at USP: 7/10/2002 **Date of Report** 7/5/2002

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	0472-0831-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083 % 3 mL	**Sample Available:**	No
Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Novaplus	**NDC Number:**	00054-8404-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02% 2.5 mL	**Sample Available:**	No
Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 055190

8/13/2003 5:44:48 PM **erf**

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Develop method to add color to lettering or print directly on nebulizers. We plan to stock in different colored baggies with a "look alike" label.

REMARKS

Problem:

Three unit-dose nebulizers are nearly identical and could easily be mistaken. The writing is small and difficult to read, uncolored, just raised lettering. Ipratopium 0.02%, 2.5 mL by Novaplus, NDC (National Drug Code) 0054-8404-11; Albuterol 0.083%, 3 mL by Alpharma, NDC 0472-0831-60; Xopenex (Levalbuterol) 1.25 mg per 3 mL, NDC 63402-513-24. No errors have been reported, but near misses have occurred.

Sepracor reply to the reporter dated December 3, 2002: Sepracor appreciates receiving this information so that we are aware of the problems and have the opportunity to give them proper attention.

MEDERR DDP REPORT

Access Number: 055173
8/13/2003 5:44:49 PM **erf**

Date Received at USP: 8/15/2002 **Date of Report** 8/12/2002

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** Unit-dose
Manufacturer: Astra Zeneca	**NDC Number:** 0186-1988-04
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.25 mg/2 mL	**Sample Available:** No

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** Unit-dose
Manufacturer: Astra Zeneca	**NDC Number:** 0186-1989-04
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.5 mg/2 mL	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055173

8/13/2003 5:44:49 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

A bulletin will be distributed to pharmacy staff regarding the potential error of confusion between strengths.

REMARKS

Problem:

Differentiation between Pulimicort Respules 0.25 mg per 2 mL and 0.5 mg per 2 mL is difficult to identify (hard to read strength imprinted on top). Dosing indicated on each individual ampule is only on top piece with no color contrast. The error discovered during a medication cart check.

MEDERR DDP REPORT

Access Number: 055077
8/13/2003 5:44:49 PM **erf**

Date Received at USP: 5/29/2002 **Date of Report** 5/29/2002

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	00487-9501-03
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	00457-9801-30
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055077

8/13/2003 5:44:49 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

We recently switched to your product because of advantageous pricing over their previous brand (Dey). However, the Dey product packaging is much more distinct between their Albuterol and their Ipratropium such that the price difference becomes negligible, given the potential for error. We will be switching back immediately to the Dey products until such time as your packaging issues are resolved.

REMARKS

Problem:

I am writing to call attention to a potential serious labeling issue regarding two of your products: Ipratroprium Bromide 0.02% 30 x 2.5 mL NDC (National Drug Code) number 00487-9801-30 and Albuterol Sulfate 0.083% 30 x 3 mL NDC number 00487-9501-03. The two products are packaged almost identically and can easily be mistaken for each other, once the inner foil pouches are opened. Both vials are in clear plastic snap vials, with the labeling consisting of raised plastic lettering. The only distinguishing characteristic between the two products is that the Albuterol vial has a raised letter "A" on the snap top and the Ipratroprium vials has a raised letter "I."

Nephron Pharmaceuticals Corporation reply to the reporter dated October 2, 2002: Regulatory Background: Nephron's Ipratropium Bromide Inhalation Solution, 0.02% was approved by the FDA (Food and Drug Administration) on September 27, 2001 under ANDA 75-562 . The approved product container is a clear, low-density polyethylene (LDPE) container embossed with labeling information. Embossed lettering for both of these products consumes all available labeling area, and was designed to be compliant with the current regulations [21CFR 201.10(h)(2)(I)], for small containers. One side of the container bears the identity of the drug [21CFR 201.50(a)], and the net quantity of contents [21CFR 201.51(a)]. The opposite side of the container bears the name of the manufacturer [21 CFR 201.1], and the warnings "For Oral Inhalation Only" and "Sterile." Container Embossing: Containers for both drug products are the same size (3 mL). The Albuterol Sulfate Inhalation Solution 0.083% container is a 3 mL fill. The Ipratropium Bromide Inhalation Solution 0.02% container in a 2.5 mL fill. Both containers have an engraving area of 0.43" x 1.90". The engraved lettering is a full block style, with letters .015" deep, 0.085" high, and 0.062" wide. All letters of the labeling are the same size. No preference in size is given to any specific statement. A search of current manufacturers of similar oral inhalation solution containers approved after 1997, reveal that manufacturers do not use paper labels on their vials. The vials are embossed with labeling information and are enclosed in laminated foil pouches. This action was taken either at the direction of FDA during application review, or independently by manufacturers in anticipation of the Agency's 1999 Guidance for Industry on container/closure systems for packaging drug products. The FDA was aware prior to publication that inks and adhesives may migrate through the LDPE container wall and into the product. Without a label on the vial, the only option to manufacturers is to emboss the vials with the necessary information. Although enhanced labeling information is provided with each product, (carton, product information sheet, foil pouch), Nephron cannot guarantee that the user will not discard all labeling materials prior to use. A search of oral inhalation products packaged in LDPE reveals that other manufacturers typically place their company logo or brand on the top seal. To assist the patient in identifying the product, Nephron has embossed the top seal of the container with a letter sufficient size, (0.25" tall) to be seen with the naked eye. The letter "I" designates the product as Ipratropium Bromide and the letter "A" designates the product as Albuterol Sulfate. Second Packaging: Nephron provides all of its oral inhalation products in foil pouches. The foil pouches are currently color coded for easy identification, with a representation of the vial including labeling, on the outside of the pouch. The approved foil pouch contains 30 individual vials and is intended to remain with the product during dispensing. We note that in prior complaints the end user bypassed this important packaging step by allowing respiratory therapist to routinely carry loose vials in their lab coats. Under such conditions, the manufacturer is not responsible for product contamination or misuse if the product was not retained in its intended package. Additionally, if these products are being used in an area with inadequate lighting, as in this case, we suggest that the person administering the medication move to an area with appropriate lighting. An individual foil pouch was approved for Nephron's Albuterol Sulfate Inhalation Solution, 0.5%, 0.5 mL

(ANDA 75-664). Nephron has expanded this concept to provide for individually pouched vials for all of Nephron's sterile Unit Dose or Unit-of-Use products. The information pouch contains all of the labeling information found on the 30-count pouch. Information provided to Nephron's Marketing department addressing this issue, with examples of the currently marketed products, is attached to this document. Nephron Pharmaceuticals Corporation manufacturers its products in accordance with each products approved by ANDA. Furthermore, Nephron complies with Current Good Manufacturing Practices as directed by the United States Food and Drug Administration.

MEDERR DDP REPORT

Access Number: 055288
8/13/2003 5:44:49 PM **erf**

Date Received at USP: 9/11/2002 **Date of Report** 9/9/2002

Product Name: Ipratropium Bromide
Generic Name(s): Ipratropium Bromide
Manufacturer: Roxane Laboratories
Labeler:
Dosage Form: Solution
Strength: 0.5 mg / 2.5 mL

Container Type: Plastic ampul
Container Size: 2.5 mL
NDC Number:
Adm. Route: Inhalation
Lot Number(s):
Sample Available: No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:
Respiratory therapy brought to my attention that the Roxane Laboratorie's Ipratropium Bromide inhalation solutions were hard to read. It is difficult once you open the pack on the inhalation solutions to read each individual solution.

Roxane Laboratories reply to the reporter dated October 1, 2002: It was reported that the imprints on the vial are difficult to read. The comments regarding the embossing used on the vial will be forwarded to our Product Management

MEDERR DDP REPORT

Access Number: 055288

8/13/2003 5:44:49 PM **erf**

Committee for review.

MEDERR DDP REPORT

Access Number: 055405
8/13/2003 5:44:49 PM **erf**

Date Received at USP: 11/1/2002 **Date of Report** 10/31/2002

Product Name: Albuterol Sulfate	**Container Type:** Plastic ampul
Generic Name(s): Albuterol Sulfate	**Container Size:** 3 mL
Manufacturer: Alpharma USPD, Inc.	**NDC Number:** 0472-0831-23
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.083%	**Sample Available:** No
Product Name: Albuterol Sulfate	**Container Type:** Plastic ampul
Generic Name(s): Albuterol Sulfate	**Container Size:** 3 mL
Manufacturer: Nephron Pharmaceutical Corporation	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 2.5 mg/3 mL	**Sample Available:** No
Product Name: Atrovent	**Container Type:** Plastic ampul
Generic Name(s): Ipratropium Bromide	**Container Size:** 2.5 mL
Manufacturer: Boehringer Ingelheim	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.02%	**Sample Available:** No
Product Name: Ipratropium Bromide	**Container Type:** Plastic ampul
Generic Name(s): Ipratropium Bromide	**Container Size:** 2.5 mL
Manufacturer: Alpharma USPD, Inc.	**NDC Number:** 0472-0751-30
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.02%	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

MEDERR DDP REPORT

Access Number: 055405

8/13/2003 5:44:49 PM **erf**

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:
We recommend a different unit-of-use size or color or labeling that is easier to read. We recommend different size containers for products by the same manufacturer capital "I" on twist off tab.

REMARKS

Problem:
We have identified a problem with unit-dose respiratory solutions. Nephron 2.5 mg Albuterol in 3 mL Albuterol Sulfate inhalation solution sterile. Capital "A" on twist off tab can be confused with Atrovent and is very difficult to read. These products are all clear unit-dose packages. The writing is difficult to read and the Alpharma products are in the same size clear unit-dose container. We believe this could be a source of medication errors as the packaging is so similar and very difficult to read.

Nephron Pharmaceuticals Corporation reply to USP dated January 15, 2003: Regulatory Background: Nephron's Ipratropium Bromide Inhalation Solution, 0.02% was approved by the FDA on September 27, 2001. The approved product container is a clear, low-density polyethylene (LDPE) container embossed with labeling information. Nephron's Albuterol Sulfate Inhalation Solution, 0.083% was approved by the FDA on September 17, 1997. The approved product container is a clear, low-density polyethylene (LDPE) container embossed with labeling information. Embossed lettering for both of these products consumes all available labeling area, and was designed to be compliant with the current regulations, for small containers. One side of the container bears the identity of the drug, and the net quantity of contents. The opposite side of the container bears the name of the manufacturer, and the warnings "For Oral Inhalation Only" and "Sterile." Additionally the Institute for Safe Medication Practices (ISMP), the organization that filed this complaint, applauded Nephron in their Quarterly Action Agenda: April - June 2002 as a manufacturer that provides medications as unit-doses with labeled outer packaging. Container Embossing: Containers for both drug products are the same size (3 mL). The Albuterol Sulfate Inhalation Solution 0.083% container is a 3 mL fill. The Ipratropium Bromide Inhalation Solution 0.02% container is a 2.5 mL fill. Both containers have an engraving area of 043" x 1.90" The engraved lettering is a full block style, with letters 0.015" deep, 0.085% high, and 0.062" wide. All letters of the labeling are the same size. No preference is size is given to any specific statement. A search of current manufacturers of similar oral inhalation solution containers approved after 1997, reveal that manufacturers do not use paper labels on

their vials. The vials are embossed with labeling and are enclosed in laminated foil pouches. This action was taken either at the direction of FDA during application review, or independently by manufacturers in anticipation of the Agency's 1999 Guidance for Industry on container/closure systems for packaging drug products. The FDA was aware prior to publication that inks and adhesives may migrate through the LDPE container wall and into the product. Without a label on the vial, the only option to manufacturers is to emboss the vials with the necessary information. Although enhanced labeling information is provided with each product, (carton, product information sheet, foil pouch), Nephron cannot guarantee that the user will not discard all labeling materials prior to use. A search of oral inhalation products packaged in LDPE reveals that other manufacturers typically place their company logo or brand on the top seal. To assist the patient in identifying the product, Nephron has embossed the top seal of the container with a letter sufficient size, (0.25" tall) to be seen with the naked eye. The letter "I" designates the product as Ipratropium Bromide and the letter "A" designates the product as Albuterol Sulfate. Secondary Packaging: Nephron provides all of its oral inhalation products in foil pouches. The foil pouches are currently color coded for easy identification, with a representation of the vial including labeling, on the outside of the pouch. The approved foil pouch contains 30 individual vials and is intended to remain with the product during dispensing. We note that in prior complaints the end user bypassed this important packaging step by allowing respiratory therapists to routinely carry loose vials in their lab coats. Under such conditions, the manufacturer is not responsible for product contamination or misuse if the product was not retained in its intended package. An individual foil pouch was approved for Nephron's Albuterol Inhalation Solution, 0.5%, 0.5 mL. Nephron has expanded this concept to provide for individually pouched vials for all of Nephron's sterile unit-dose and unit-of-use products. The individual pouch contains all of the labeling information found on the 30-count pouch. Information provided to Nephron's marketing department addressing this issue, with examples of the currently marketed products, is attached to this document. Nephron Pharmaceuticals Corporation manufacturers its products in accordance with each products approved ANDA. Furthermore, Nephron complies with Current Good Manufacturing Practices as directed by the United States Food and Drug Administration.

MEDERR DDP REPORT

Access Number: 055407
8/13/2003 5:44:50 PM **erf**

Date Received at USP: 11/1/2002 **Date of Report** 10/31/2002

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** 2 mL
Manufacturer: Astra Zeneca	**NDC Number:** 00186-1989-04
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.5 mg/2 mL	**Sample Available:** No

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** 2 mL
Manufacturer: Astra Zeneca	**NDC Number:** 00186-1988-04
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.25 mg/2 mL	**Sample Available:** No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? Prescriber

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Pharmacist

When and how was the error discovered? N/I

Where did the error occur? Hospital

Was another practitioner involved in the error? Yes

If yes, what type of practitioner? Pharmacist

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055407

8/13/2003 5:44:50 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

I have left this organization. My suggestion was to be sure that for these items, all strengths be listed in the computer and noted as "***n/f, change to ____strength**." But I am pretty sure that it was not heeded as this is not a major topic in error prevention yet, and at the time that I addressed it, I did not have an actual error in my hand. I do know that it has happened though and will continue happening. I am not sure what can be done to correct this. In my place of work, I have requested that the other also be listed in our computer so everyone is aware of that possibility.

REMARKS

Problem:

I feel that pharmacy employees who work within a closed system (for example, a hospital with a formulary) tend to get inbred. By inbred I mean, they know what products are on formulary and that is about it. The best example that came up recently was Budesonide nebs. Our facility does not have this product on formulary, but for some reason an entry for the 0.25 mg nebs has been added to our computer. Anyway, after a while, the orders were not being written specifying a strength, and the pharmacists in some cases were dispensing drug as 0.25 mg nebs since that was the only product they were familiar with. Part of the problem is that the pharmacists in a larger facility do not need to worry about making the order from the wholesaler, and therefore, never have to acknowledge the different (but similar) products.

MEDERR DDP REPORT

Access Number: 055701
8/13/2003 5:44:50 PM **erf**

Date Received at USP: 2/25/2003 **Date of Report** 2/24/2003

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0831-23
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.83%	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055701

8/13/2003 5:44:50 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

We changed supplier to Dey.

REMARKS

Problem:

This is regarding a potential error with respiratory medications that we have eliminated at our organization. The potential error was realized through the conduct of a FMEA. The use of unit-of-use respiratory medications brings with them the potential for an error due to look-alike packaging. We recently reviewed all of these agents and found that two products, Ipratropium 0.02% packaged by Nephron and Albuterol 0.083% packaged by Alpharma, were indistinguishable due to their packaging and poor labeling. When we met with our respiratory therapists, our alarms were further heightened when we heard of the potential of a therapist digging through his/her pockets/bin in the evening hours under low lighting conditions in hopes of administering the correct medication. Upon this review, we immediately switched our vendor of all unit-of-use respiratory medications to Dey. Each of their products contains a label which is clearly distinguishable and easy to read which is affixed to each unit-of-use package.

MEDERR DDP REPORT

Access Number: 055756
8/13/2003 5:44:50 PM **erf**

Date Received at USP: 3/10/2003 **Date of Report** 3/10/2003

Product Name:	Atrovent	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Boehringer Ingelheim Pharm., Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055756

8/13/2003 5:44:50 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Change the packaging and make it easier to read.

REMARKS

Problem:

Unable to read the label, and the packaging is the same. This was discovered when the registered nurse spoke to hospital pharmacist.

Roxane Laboratories reply to the reporter dated March 26, 2003: Your comments regarding our vial will be forwarded to our Product Management Committee for review.

Sepracor Inc. reply to the reporter dated May 19, 2003: The current packaging for Xopenex (Levalbuterol HCl) inhalation solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (green for the 0.31 mg/3 mL, yellow for the 0.63 mg/3 mL and red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. The strengths can be easily differentiated in well-lit areas. In order to increase the visible differentiation of the product, Sepracor has evaluated several changes. However, we have yet to clearly determine a way to make the information more readily visible without an increase in cost to the consumer. Please be aware that many product changes, including labeling changes such as this, require FDA approval before being marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 055762
8/13/2003 5:44:50 PM **erf**

Date Received at USP: 3/12/2003 **Date of Report** 2/1/2003

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	24 ampuls
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? Physician

Describe Outcome: The patient did not take the medicine.

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Family member/caregiver

When and how was the error discovered? The grandmother saw the wrong strength dispensed, called another pharmacist from a different store, and notified me.

Where did the error occur? Pharmacy, community

Was another practitioner involved in the error? Yes

If yes, what type of practitioner? Pharmacist

Was patient counseling provided? Yes

If yes, before or after error was discovered? After

Number of occurrences:

Patient information that might be relevant:
The patient is a 15-year-old female diagnosed with asthma.

MEDERR DDP REPORT

Access Number: 055762

8/13/2003 5:44:51 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Slow down when calling MD for strength, make correct strength more clear to R.Ph. checking prescription.

REMARKS

Problem:

Medication was presented for Xopenex for a patient on Month/XX/XX. There was no strength on prescription. The R.Ph. (registered pharmacist) wrote both strengths on prescription, called MD, then circled correct strength. When verifying prescription, I quickly glanced at one strength and dispensed the 1.25 mg. The doctor wanted 0.63 mg. The pharmacist from another location notified me of the mistake, and I tried to contact the patient to no avail. About a month later, the patient returned the medication, I apologized and gave her a refund.

MEDERR DDP REPORT

Access Number: 055777
8/13/2003 5:44:51 PM **erf**

Date Received at USP: 3/26/2003 **Date of Report** 3/26/2003

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Zenith Goldline	**NDC Number:**	00172-6405-49
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083% (2.5 mg/3 mL)	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Zenith Goldline	**NDC Number:**	00172-6407-49
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%(0.5 mg/2.5 mL)	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055777

8/13/2003 5:44:51 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

We are marking them with a magic marker to distinguish the two. It would be nice if they could make one vial longer than the other, or at least look different.

REMARKS

Problem:

Albuterol Sulfate and Ipratropium Bromide, both made by ZenithGoldline, have identical packaging. Both medications are used daily in our facility. This is a potential error waiting to happen. The identical items were discovered by our respiratory therapy department head on the nursing floor at the hospital.

MEDERR DDP REPORT

Access Number: 055780
8/13/2003 5:44:51 PM **erf**

Date Received at USP: 3/27/2003 **Date of Report** 3/26/2000

Product Name:	Pulmozyme	**Container Type:**	Plastic ampul
Generic Name(s):	Dornase Alfa	**Container Size:**	2.5 mL
Manufacturer:	Genentech	**NDC Number:**	50242-0100-39
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	2.5 mg/2.5 mL	**Sample Available:**	No

Product Name:	Tobi	**Container Type:**	Plastic ampul
Generic Name(s):	Tobramycin	**Container Size:**	5 mL
Manufacturer:	Chiron Corporation	**NDC Number:**	53905-0065-01
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	300 mg/5 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055780

8/13/2003 5:44:51 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Products should be labeled differently.

REMARKS

Problem:

Safety team doing a walk-around interview of staff spoke to a respiratory therapist about issues of safety to patients or staff. The therapist voiced concern about the products Tobi and Pulmozyme looking almost identical. They are both used by therapists, stored in the refrigerator, and even if held side by side look almost identical. No actual error at this time but very likely it will occur sometime.

MEDERR DDP REPORT

Access Number: 055809
8/13/2003 5:44:51 PM **erf**

Date Received at USP: 4/10/2003 **Date of Report** 4/10/2003

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	0487-9501-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	0487-9801-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 055809

8/13/2003 5:44:51 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Use different colored plastic for each product and add small paper label with bar code so that the respiratory therapist or nurse can scan the product at time of administration.

REMARKS

Problem:

Poor labeling of the products may cause a patient to receive the wrong medicine. Albuterol and Ipratropium Solutions are packaged in unit-of-use polyethylene vials with the product information molded into the plastic. This information is extremely difficult to read in bright light and almost impossible under the conditions typically found on a nursing unit. The twist off tab at the tip of each vial contains a large "A" or "I" molded into it, but only on one surface of the tag.

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 055988

4/13/2004 12:09:10 PM **erf**

Date Received at USP 7/8/2003 **Date of Report** 3/20/2003

Product Name:	Acetaminophen	**Container Type:**	Foil wrap
Generic Name(s):	Acetaminophen	**Container Size:**	
Manufacturer:	G & W Laboratories	**NDC Number:**	
Labeler:		**Adm. Route:**	Rectal
Dosage Form:	Suppository	**Lot Number(s):**	
Strength:		**Sample Available:**	Yes

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083% (2.5 mg/3 mL)	**Sample Available:**	Yes

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083% (2.5 mg/3 mL)	**Sample Available:**	Yes

Product Name:	Bactroban Nasal	**Container Type:**	Plastic ampul
Generic Name(s):	Mupirocin Calcium	**Container Size:**	1 gram
Manufacturer:	Glaxo SmithKline	**NDC Number:**	
Labeler:		**Adm. Route:**	Nasal
Dosage Form:	Ointment	**Lot Number(s):**	
Strength:	2%	**Sample Available:**	Yes

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MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 055988

4/13/2004 12:09:10 PM **erf**

Product Name:	Compazine	**Container Type:**	Foil wrap
Generic Name(s):	Prochlorperazine	**Container Size:**	
Manufacturer:	SmithKline Beecham	**NDC Number:**	
Labeler:		**Adm. Route:**	Rectal
Dosage Form:	Suppository	**Lot Number(s):**	
Strength:	5 mg	**Sample Available:**	Yes

Product Name:	Depakote	**Container Type:**	Unit-dose
Generic Name(s):	Divalproex Sodium	**Container Size:**	
Manufacturer:	Abbott Laboratories	**NDC Number:**	
Labeler:		**Adm. Route:**	Oral
Dosage Form:	Tablet, delayed release/enteric coated	**Lot Number(s):**	
Strength:	500 mg	**Sample Available:**	Yes

Product Name:	Dilantin	**Container Type:**	Unit-dose
Generic Name(s):	Phenytoin Sodium	**Container Size:**	
Manufacturer:	Parke-Davis	**NDC Number:**	
Labeler:		**Adm. Route:**	Oral
Dosage Form:	Capsule, extended release	**Lot Number(s):**	
Strength:	100 mg	**Sample Available:**	Yes

Product Name:	Diovan	**Container Type:**	Unit-dose
Generic Name(s):	Valsartan	**Container Size:**	
Manufacturer:	Novartis Pharmaceuticals	**NDC Number:**	
Labeler:		**Adm. Route:**	Oral
Dosage Form:	Tablet	**Lot Number(s):**	
Strength:	80 mg	**Sample Available:**	Yes

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Access Number: 055988

4/13/2004 12:09:10 PM **erf**

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%(0.5 mg/2.5 mL)	**Sample Available:**	Yes

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%(0.5 mg/2.5 mL)	**Sample Available:**	Yes

Product Name:	Pilocar	**Container Type:**	Plastic ampul
Generic Name(s):	Pilocarpine Hydrochloride	**Container Size:**	
Manufacturer:	Ciba Vison	**NDC Number:**	
Labeler:		**Adm. Route:**	Ophthalmic
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	4%	**Sample Available:**	Yes

Product Name:	Refresh	**Container Type:**	Plastic ampul
Generic Name(s):	Polyvinyl Alcohol Povidone	**Container Size:**	
Manufacturer:	Allergan	**NDC Number:**	
Labeler:		**Adm. Route:**	Ophthalmic
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	Yes

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Access Number: 055988

4/13/2004 12:09:10 PM **erf**

Product Name:	Sodium Chloride	**Container Type:**	Plastic ampul
Generic Name(s):	Sodium Chloride	**Container Size:**	
Manufacturer:	Ballard Medical Products Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.9%	**Sample Available:**	Yes

Product Name:	Sodium Chloride	**Container Type:**	Plastic ampul
Generic Name(s):	Sodium Chloride	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.9%	**Sample Available:**	Yes

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	Yes

Was the medication administered to or used by patient?

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered

Where did the error occur? N/A

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 055988

4/13/2004 12:09:10 PM **erf**

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Standardization of expiration, standardization of med labels, and contrast on label. Position on label standard. Approval with label. Printed with ink (no stamping).

REMARKS

Problem:

Product(s) involved: Ipratropium Bromide inhalation solution (Nephron Pharm Corp & Dey Labs); Albuterol Sulfate inhalation solution (Dey Labs & Alpharma); Refresh ophthalmic (Allergan); Acetaminophen rectal suppositories (G & W Labs); Pilocar ophthalmic solution (Ciba Vision); Diovan tablets (Novartis); Bactroban nasal ointment (GlaxoSmithKline); Sodium Chloride inhalation solution (Ballard Medical Products & Dey Labs); Depakote tablets (Abbott Labs); Dilantin capsules (Parke-Davis); Compazine rectal suppositories (SmithKline Beecham); and Xopenex (Sepracor). In a continuing effort to assure patient safety and to prevent subpotent or toxic medications from being dispensed, I am reporting a potentially dangerous situation. It has probably come to the attention of many professionals and yet continues to appear on our indications. This is the poor or non-legibility of expiration dates on various medication packages or containers. In the hospital setting, we deal with thousands of doses, individually packaged and dated, requiring monthly checking and weeding out of those expired or near expirations. The packages not adequately stamped or printed must be read in a variety of lighting situations throughout the building by pharmacists and nurses, taking much unnecessary time to identify the dates, some of which are lightly imprinted. In some cases, the units cannot be used due to inadequate markings (i.e., microscopic print, weak printing, weak stamping, difficult labeling [scrambled printing], dose not readable, stippled surface printed on, light print on white or shiny surface, stamp on crimp of tube [white on white, or shiny on shiny, or non-identifiable], ophthalmic plastic single-dose container with information molded on [no contrast]). The importance of accuracy and safety of dispensing medications cannot be emphasized enough. It would appear that the manufacturers would be concerned through liability on proper labeling. In reporting this, I am aware that it is not a new situation, but it is one that has seen no improvement. Ironically, it seems to be expanding in new packaging of unit-dose ointment, eye meds, single-use externals and even unit-dose oral medication. We are under the impression that labels on new products are approved before release and wonder if expiration and lot number are included. Our concerns in the hospital setting are to do no harm, and in this context, we are on notice to report our concerns. Illegible expiration dates on these products/medications. Some molded into plastic package. Some too small to read. Some on foil wrapper; many can only be read under ideal lighting conditions. Also, packages are over wrapped with clear plastic over expiration dates; cannot see stamped dates. Lot numbers are difficult to impossible to read through the plastic. In case of recall, they would be impossible to retrieve. Name of med and/or expiration dates molded on package. Extremely difficult, impossible under low light conditions are Ipratropium by Nephron Pharm Corp and Sodium Chloride inhalation solution by Ballard/Kimberly Clark.

GlaxoSmithKline reply to the reporter dated August 8, 2003: Upon checking with our package engineering department, it was confirmed that this information is clearly noted on each box containing ten tubes. Actually, this medication should be used by a single patient, one tube daily, for ten days. Since the information you questioned is printed on every box of ten tubes, we feel that our responsibility has been properly met.

Pfizer Inc reply to the reporter dated August 8, 2003: This report has been brought to the attention of the appropriate

management and packaging development personnel.

Sepracor Inc. reply to the reporter dated August 25, 2003: The current packaging for Xopenex (Levalbuterol Hydrochloride) inhalation solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (green for the 0.31 mg/3 mL, yellow for the 0.63 mg/3 mL, and red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. The strengths can be easily differentiated in well-lit areas. In order to increase the visible differentiation of the product, Sepracor has evaluated several changes. However, we have yet to clearly determine a way to make the information more readily visible without an increase in cost to the consumer. Please be aware that many product changes, including labeling changes such as the lot number and expiration date, require FDA approval before being marketed to consumers and therefore require additional time to implement.

Allergan reply to the reporter dated September 15, 2003: Allergan is committed to an ongoing program to improve the legibility of our unit-dose container labeling. The timing for completion of this ongoing project is not known at this time.

GlaxoSmithKline reply to the reporter dated September 16, 2003: As a corrective action, the white laminated aluminum foil was changed to a silver colored aluminum foil.

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 056052

4/13/2004 12:09:11 PM **erf**

Date Received at USP 8/25/2003 **Date of Report** 8/25/2003

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra Zeneca	**NDC Number:**	0186-1989-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.5 mg/2 mL	**Sample Available:**	No

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra Zeneca	**NDC Number:**	0186-1988-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.25 mg/2 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered

Where did the error occur? N/A

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

At this point, being aware of the potential is our biggest defense. RTs have been alerted to the potential and to take a

MEDERR DDP REPORT

Access Number: 056052

4/13/2004 12:09:11 PM **erf**

second look when using a particular strength. It was actually the pharmacists who notified me of the potential for error. It's a mind-set we have established, start "putting yourself in their shoes", "what if scenarios."

REMARKS

Problem:

I would like to report a potential error-prone packaging issue: The packaging for Pulmicort respules 0.5 mg and 0.25 mg is difficult to read once the unit-of-use suspension is removed from the package outer wrap. Most respiratory therapists will carry these in their fanny packs or cases, and they look exactly alike. A danger exists that can result in the wrong dose (either double the dose or 1/2 the dose). These types of packaging are problematic as they look so much alike, and the raised lettering is difficult to read. The NDC numbers of the products in question are: 0186-1988-04 for the 0.25 mg/2 mL and 0186-1989-04 for the 0.5 mg/2 mL. Since we had not seen error reports, it's difficult to say if errors have occurred. We had been using this product for only a couple of weeks.

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 056074

4/13/2004 12:09:11 PM **erf**

Date Received at USP 9/16/2003 **Date of Report** 8/12/2003

Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:** 3 mL
Manufacturer: Sepracor Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.63 mg/3 mL	**Sample Available:** No

Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:** 3 mL
Manufacturer: Sepracor Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 1.25 mg/3 mL	**Sample Available:** No

Was the medication administered to or used by patient? No

What type of staff or health care practitioner made the initial error? Pharmacist

Describe Outcome: None

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Family member/caregiver

When and how was the error discovered The mother of patient noticed that it was the wrong dose.

Where did the error occur? Pharmacy, community

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Male, approximately 10 months old

Reporter's recommendations or policies to prevent future similar errors:

Realized two days per month was not frequent enough to work retail. Quit working until able to work more hours.

MEDERR DDP REPORT

Access Number: 056074

4/13/2004 12:09:11 PM **erf**

REMARKS

Problem:

Accidentally entered dosage of Xopenex as 1.25 mg/3 mL instead of 0.63 mg/3 mL. Mother of patient noticed. Prescription was changed to the correct dose. It was a busy weekend. Possible error cause(s) and contributing factor(s): Only worked at pharmacy two days per month.

Sepracor reply to USP dated October 31, 2003: This error was due to the pharmacist entering the prescription wrong into the computer and not from the Xopenex being mislabeled.

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 056075

4/13/2004 12:09:11 PM **erf**

Date Received at USP 9/16/2003 **Date of Report** 8/12/2003

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** 2 mL
Manufacturer: Astra Zeneca	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.25 mg/2 mL	**Sample Available:** No

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:** 2 mL
Manufacturer: Astra Zeneca	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.5 mg/2 mL	**Sample Available:** No

Was the medication administered to or used by patient? Yes

What type of staff or health care practitioner made the initial error? Pharmacist

Describe Outcome: No harm.

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Pharmacist

When and how was the error discovered Pharmacist noticed the error the next day and called the patient's mother.

Where did the error occur? Pharmacy, community

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Male, approximately 10 months old.

Reporter's recommendations or policies to prevent future similar errors:

After the error, I realized that if I was going to work retail, I needed to work more than two days per month and left

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MEDERR DDP REPORT

Access Number: 056075

4/13/2004 12:09:11 PM **erf**

the pharmacy until that is possible.

REMARKS

Problem:

I was working on a busy weekend with technician. Entered new Pulmicort prescription in computer as 0.5 mg/2 mL instead of 0.25 mg/2 mL. I was doing inventory the next day, realized that the wrong dose was dispensed, called patient's mother and physician to resolve the issue. Prescription was replaced with the correct one. Possible error cause(s) and contributing factor(s): Worked as a retail pharmacist two days per month.

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 056129

4/13/2004 12:09:11 PM **erf**

Date Received at USP 10/22/200 **Date of Report** 10/22/200

Product Name: Xopenex	**Container Type:** Plastic ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:**
Manufacturer: Sepracor Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: Various	**Sample Available:** No

Product Name: Albuterol Sulfate	**Container Type:** Plastic ampul
Generic Name(s): Albuterol Sulfate	**Container Size:**
Manufacturer: Alpharma USPD, Inc.	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.083%	**Sample Available:** No

Was the medication administered to or used by patient?

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered

Where did the error occur? N/A

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

MEDERR DDP REPORT

Access Number: 056129

4/13/2004 12:09:11 PM erf

REMARKS

Problem:

Xopenex and Albuterol (Alpharma) unit-dose vials for inhalation are both packaged in clear plastic inhalation vials. The drug name and dosage are imprinted on both items. It is very difficult to read as there is no color or lettering to the vial. We have not had an actual error in regards to these medications. However, we see it as a serious potential error.

Sepracor reply to USP dated January 20, 2004: The current packaging for Xopenex (Levabuterol Hydrochloride) inhalation solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (green for the 0.31 mg/3 mL, yellow for the 0.3 mg/3 mL and red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. The strengths can be easily differentiated in well-lit areas. Sepracor is currently evaluating additional changes to further differentiate Xopenex from other products. One of the distinct changes being considered by Sepracor is putting a very visible letter "X," representing Xopenex, on top on the unit-dose vial. Please be aware that changes such as these require FDA approval before being marketed to consumers and therefore require additional time to implement.

Alpharma US Pharmaceutical Division reply to USP dated December 16, 2003: We would like to note that each manufacturer of pharmaceuticals designs their labels and packaging to provide a corporate identity and to prevent confusion among brands. This is consistent throughout the industry. Alpharma USPD's brands of inhalation products are identifiable by the color coding of the outer boxes and foil wrapper (blue for Albuterol and green for Ipratropium Bromide). As the unit-dose vial has been designed to provide a sterile product, the product name, lot number and expiration date are embossed in the plastic in raised letters that also provide a textured surface to assist in gripping the vial when opening by twisting off the top. These respiratory care products are designed in this manner to permit the packaging of a sterile product. The product cartons and foil packages to protect these products from light are clearly marked with the product name and dosage. Alpharma recommends keeping the products in the foil wrappers to prevent any possibility of product degradation from exposure to light and to help prevent errors in dispensing medication in vials. Our packaging for each product meets or exceeds all current regulatory requirements and has been approved by the FDA. However, as a courtesy to our customers, effective Q4 2002, the vials for Albuterol Sulfate Inhalation Solution 0.083% were changed. The top of the vial is now in the shape of an "A."

MEDERR DDP REPORT

This document is released pursuant to the USP Document Disclosure Policy.

Access Number: 056205

4/13/2004 12:09:11 PM

erf

Date Received at USP 12/2/2003 **Date of Report** 12/2/2003

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:**
Manufacturer: Astra Zeneca	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.25 mg/2 mL	**Sample Available:** No

Product Name: Pulmicort Respules	**Container Type:** Plastic ampul
Generic Name(s): Budesonide	**Container Size:**
Manufacturer: Astra Zeneca	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Suspension	**Lot Number(s):**
Strength: 0.5 mg/2 mL	**Sample Available:** No

Was the medication administered to or used by patient?

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered

Where did the error occur? N/A

Was another practitioner involved in the error

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Individual unit-dose containers are placed in brown bags for protection from light and dispensed to the nursing unit.

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MEDERR DDP REPORT

Access Number: 056205 **erf**

4/13/2004 12:09:11 PM

The order is usually filled by a pharmacy technician and is always checked by a pharmacist before it leaves the pharmacy.

REMARKS

Problem:

Pulmicort Respules (Budesonide) come in unit-dose containers that are nearly identical. We (pharmacy department at a hospital) noted the potential for error when we first started stocking the product. We brought it to the attention of the sales representative at that time. The representative said he would take the request for different packaging back to his company. After not hearing anything, I called the manufacturer and pointed out the potential problem. As far as I know, my call was noted but nothing has changed in terms of packaging. Recently, a nurse expressed concern that she may administer the wrong dose because the labeling is nearly impossible to read. Several members of the pharmacy and nursing staff have complained about the difficulty in reading the label and the potential for error. While I am not aware of any errors that reached the patient, I doubt that an error would be detected due to the difficulty of reading the package labeling. Potential error cause(s) and contributing factor(s): The container is made of clear plastic with no ink on the container--only embossed letters; this is very difficult to read in the first place. The only difference in product labeling is the "0.25" or "0.5."