



**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 14, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: White & Blue Lion, Inc. – RECALL [Medical Device]

**AFFECTED
PRODUCT:** Tattoo Inks and tattoo needles

SUMMARY: Unclassified Recall; The recall is due to pathogenic bacterial contamination.

| <u>Tattoo Inks</u> <u>sold in kits and separately)</u> | <u>Brand</u> | <u>Code</u> | <u>Size</u> |
|---|---|---|-------------|
| All Colors | Multi colored Chinese Dragon Image with black and white lettering | Lot No. OR20036 Batch #8 Best if used by 16/12/16 | 5 ml bottle |

| <u>Tattoo Needles</u> <u>(included in kits)</u> | <u>Brand</u> | <u>Codes</u> | <u>Lot No</u> | <u>Expiration</u> |
|--|---|--|--|-------------------|
| Individually packaged in groups of 5 | None – labeled as “CE0197 Pre-made tattoo needle” “sterilized by E.O. Gas” | Art No. 1203RL, 1205M, 1205RL, 1205RS, 1209RL, 1207RL, 1207M, 1207RS, 1209M, 1209RS | 201308, 201307, 201312, 201402, 201311, 201310 | JUN2018 |

The inks and needles are sold in tattoo kits and the inks are also sold separately by 8Decades and White & Blue Lion, Inc. through www.amazon.com - Nationwide.

SUGGESTED

ACTION: For consumer inquiry only. Consumers with any questions should contact us at 1-626-586-3485 from Monday to Friday between the hours of 9am to 6pm PST.



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www.statehealth.in.gov

To promote and provide
essential public health services.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Voluntary Nationwide Recall of Tattoo Ink, Tattoo Needles, Tattoo kits Due to Microbial Contamination

Contact:
Consumer:
1-626-586-3485

Media:
1-626-586-3485

FOR IMMEDIATE RELEASE - July 11, 2014 - July 11, 2014- White & Blue Lion, Inc. in the City of Industry, CA is recalling all lots of tattoo Inks and tattoo needles due to pathogenic bacterial contamination. Use of these products may cause bacterial infection and can lead to sepsis, a potentially life-threatening complication of an infection. The recall includes all tattoo inks, tattoo needles, and tattoo kits distributed by White & Blue Lion including the ones specifically listed below:

| Tattoo Inks sold in kits and separately) | Brand | Code | Size |
|--|---|---|-------------|
| All Colors | Multi colored Chinese Dragon Image with black and white lettering | Lot No. OR20036 Batch #8 Best if used by 16/12/16 | 5 ml bottle |

| Tattoo Needles (included in kits) | Brand | Codes | Lot No | Expiration |
|--------------------------------------|---|---|--|------------|
| Individually packaged in groups of 5 | None – labeled as “CE0197 Pre-made tattoo needle” “sterilized by E.O. Gas” | Art No. 1203RL, 1205M, 1205RL, 1205RS, 1209RL, 1207RL, 1207M, 1207RS, 1209M, 1209RS | 201308, 201307, 201312, 201402, 201311, 201310 | JUN2018 |

The inks and needles are sold in tattoo kits and the inks are also sold separately by 8Decades and White & Blue Lion, Inc. through www.amazon.com.

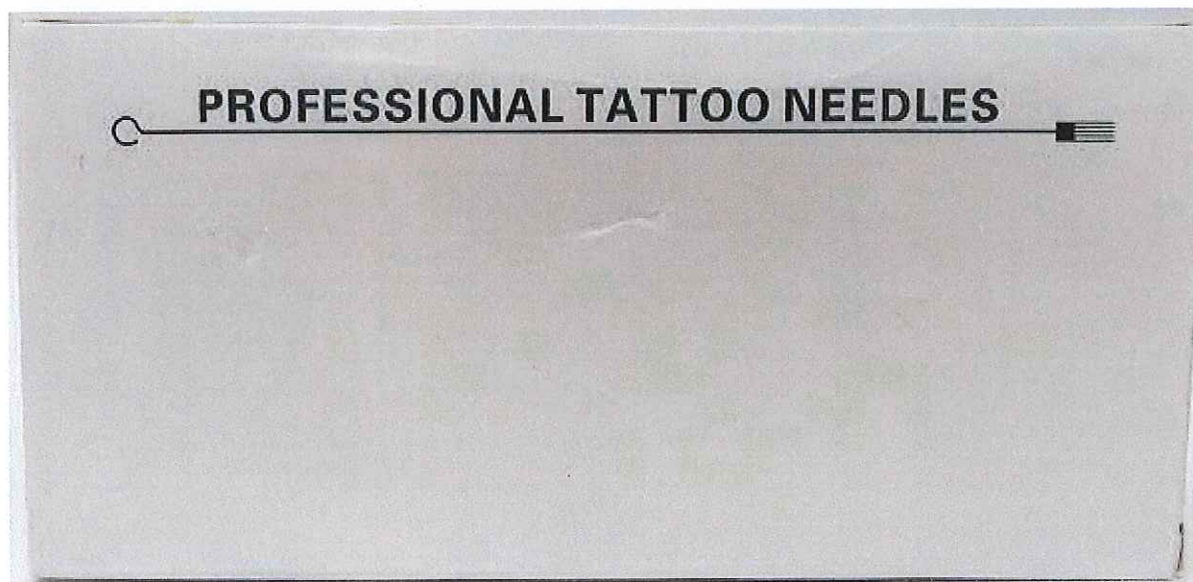
There was a report of one illness as of today's date.

FDA Laboratory testing has found microbial bacterial contamination in both the inks and needles.

This recall is being made with the knowledge of the US Food and Drug Administration.

Consumers with any questions should contact us at 1-626-586-3485 from Monday to Friday between the hours of 9am to 6pm PST.

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Photos





STERILE TATTOO NEEDLES



To Remove Needle:

1. Peel back the paper cover from plastic blister.
2. Storage: Avoid humidity and high temperature.
3. Do not use if inside package is damaged.

ITEM NO.:

QTY: 50PCS









TATTOO

Ingredients: Distilled Water,
Alcohol, And Glycerin

Cl: #19746

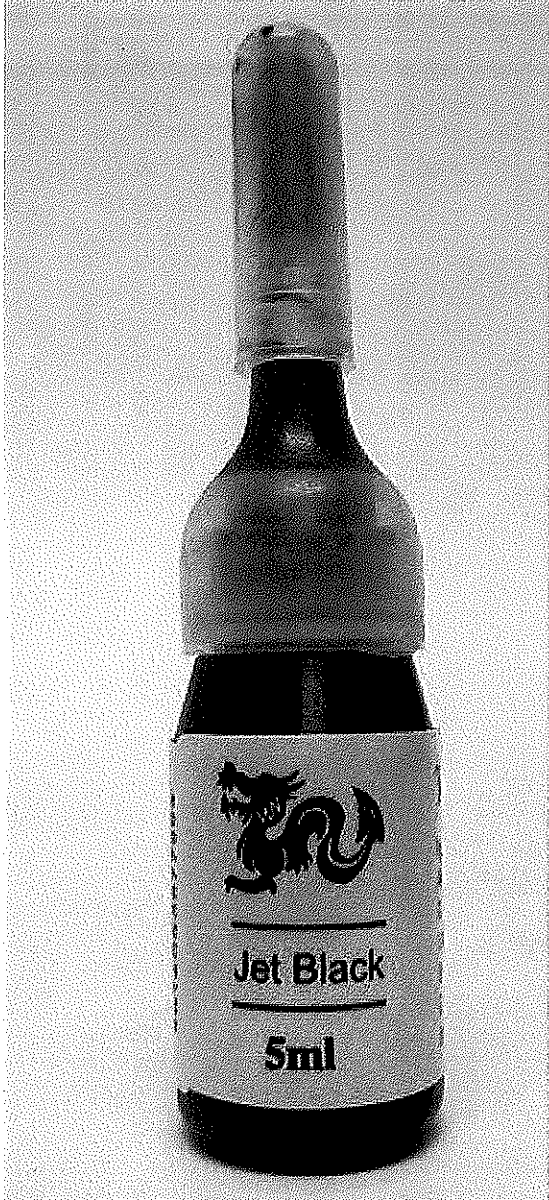
Lotch: #OR20036

Batch: #8

Date Produced: 20/02/13

Best If Used By: 16/12/16





Jet Black

5ml

TATTOO

Ingredients: Distilled Water
Alcohol, And Glycerin

CI: #19746

Lotch: #OR20036

Batch: #8

Date Produced: 20/02/13

Best If Used By: 16/12/16

