



TRANSMITTED VIA FACSIMILE

NOV 21 2000

Ms. Barbara Goulding  
Supervisor, Regulatory Affairs  
American Regent Laboratories, Inc.  
One Luitpold Drive  
Shirley, New York 11967

RE: **NDA 21-135**  
Venofer (Iron Sucrose Injection)  
**MACMIS ID # 9526**

Dear Ms. Goulding:

This letter addresses the dissemination by American Regent Laboratories, Inc., (ARL) of a "reminder" advertisement for Venofer (iron sucrose injection), identified as TAV-2340A. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program and has concluded that the advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the drug product. The reminder advertisement for Venofer injection includes the words, "new" and "the foundation for the future." Thus, the advertisement makes a representation about the product.

Promotional materials must also be submitted to DDMAC for review at the time of initial dissemination in compliance with 21 CFR Sec. 314.81. Our records indicate that this promotional material has not yet been submitted for review.

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DDMAC requests that ARL immediately cease using this advertisement and all other promotional materials for Venofer that contain the same or similar claims or presentations. You should submit a written response to DDMAC, on or before December 6, 2000, describing its intent and plans to comply with the above. In its letter to DDMAC, you should include a list of all promotional materials that were discontinued, and the discontinuation date.

ARL should direct its response to Patricia Staub by facsimile at (301) 594-6759, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS #9526 and the NDA number.

Sincerely,

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/S/

Patricia Kuker Staub, R.Ph, J.D.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising, and Communications

**THE FOUNDATION  
FOR THE FUTURE**

**New**

**Venofer<sup>®</sup>**

*iron sucrose injection*

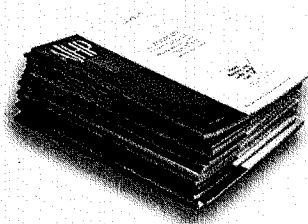
**COMING SOON FROM**

**AMERICAN  
REGENT**  
LABORATORIES, INC.

One Luitpold Drive • Shirley, NY 11967

**800-645-1706**

# In This Issue



## **for Acute Care Pharmacists**

- DHEA: Dehydroepiandrosterone
- Pricing of blood products
- Pharmacology and therapeutic use of trastuzumab in breast cancer
- Responsible use of blood products in response to supply and demand

## **for Ambulatory Care Pharmacists**

- DHEA: Dehydroepiandrosterone
- Pharmacology and therapeutic use of trastuzumab in breast cancer
- Medication sample labeling practices
- Re-engineering an ambulatory care pharmacy practice

## **for Clinical Specialists**

- Pharmacology and therapeutic use of trastuzumab in breast cancer
- Responsible use of blood products in response to supply and demand
- Pricing of blood products
- Survey of ASHP-accredited pharmacy residency programs
- DHEA: Dehydroepiandrosterone

## **for Home Care Practitioners**

- Pricing of blood products
- Responsible use of blood products in response to supply and demand
- DHEA: Dehydroepiandrosterone

## **for Long-Term-Care Pharmacists**

- DHEA: Dehydroepiandrosterone

## **for Managed Care (HMO, PPO, PBM) Pharmacists**

- Pricing of blood products
- Responsible use of blood products in response to supply and demand
- DHEA: Dehydroepiandrosterone
- Pharmacology and therapeutic use of trastuzumab in breast cancer
- Medication sample labeling practices

## **for Pharmacy Practice Managers**

- Pricing of blood products
- Responsible use of blood products in response to supply and demand
- Medication sample labeling practices

## **for Students**

- Survey of ASHP-accredited pharmacy residency programs
- Pharmacology and therapeutic use of trastuzumab in breast cancer

## **for Technicians**

- Medication sample labeling practices
- DHEA: Dehydroepiandrosterone