

O'NEILL & BORGES

AMERICAN INTERNATIONAL PLAZA
250 MUÑOZ RIVERA AVENUE, STE 800
SAN JUAN, PUERTO RICO 00918-1813
TELECOPIER: (787) 753-8944

CLIENT BRIEFING

June 11, 2008

Proposed Local Regulation

RE: *Puerto Rico Department of Health - Regulation for the Licensing and Control of Establishments and Persons who Manufacture, Distribute, Dispense and Sell Drugs and Devices*

On June 7, 2008, the Puerto Rico Department of Health (the "Department") issued a public notice announcing its intent to adopt regulations for the licensing and control of establishments and persons who manufacture, distribute, dispense and sell drugs and devices (the "Regulation"). The Regulation will abolish regulations previously adopted by the Department regarding the foregoing matter.

The proposed Regulation includes modifications affecting the general requirements for the procurement of licenses such as Pharmaceutical Industry, Biological Products and Dispensary licenses, among others. The Regulation also modifies health-related regulatory provisions concerning, among other things, the manufacture, handling, and storage of drugs, and contains enforcement provisions.

The Department will receive written comments and/or recommendations on the proposed Regulation until July 7, 2008. Further, the Department will hold a public hearing on June 23, 2008 at the Department of Health, Old Psychiatric Hospital, at the Medical Center complex in Río Piedras.

If you need additional information on the Regulation, its potential impact and applicability to your operations, or would like to prepare and file comments, please contact any of the attorneys at the O'Neill & Borges Environmental Law and Litigation Practice Group.

Jorge L. San Miguel	(787) 282-5745	Irwin H. Flashman	(787) 282-5710
Lillian Mateo-Santos	(787) 282-5729	Pedro J. Nieves	(787) 282-5751
Isis L. Pérez-Vélez	(787) 282-5768	Luis R. Rivera	(787) 282-5789

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