DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division of International Drug Quality
International Compliance Branch
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July 22, 2011

Mr. Ing. Daniel Haymann
C.E.O. and President
Laboratorios Haymann S.A.
Gianelli 1489
Montevideo
Uruguay

FEI: 3004000118

Dear Mr. Haymann:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your finished dosage and active pharmaceutical ingredient manufacturing facility in Montevideo, Uruguay by FDA Investigator Ernest Bizjak, during the period of May 16-19, 2011. An FDA-483, Notice of Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company's response dated June 24, 2011 with supportive documentation. Based on the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by FDA in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or telephone number.

Sincerely,

Steven Thurber
Consumer Safety Officer
International Compliance Branch

Enclosure: EIR

Primera y Única Planta Farmacéutica Uruguaya APROBADA POR LA U.S. FDA

FDA SUCCESSFULLY INSPECTED

En nuestro constante compromiso con la excelencia, anunciamos con orgullo el logro de la obtención de aprobación de nuestra planta por parte la de la ***US FDA*** (Food and Drug Administration de los Estados Unidos)

Esta certificación de aprobación se logra tras años de esfuerzo, mediante capacitación continua, inserción de avanzadas tecnologías y estricto cumplimiento de las Normas cGMP (Buenas Prácticas de Manufactura) de FDA y GMP de la OMS

Nuestra planta farmacéutica también ha sido de las primeras en recibir la aprobación sanitaria en cada uno de los países miembros del Mercosur: Argentina, Brasil, Paraguay y Uruguay.

Con el sólido respaldo de esta nueva aprobación - inédita para países de Sudamérica - podemos acceder a mercados en los que el rótulo "Made in Uruguay" aún no había sido aplicado a medicamentos.

LABORATORIOS HAYMANN S.A.

VOLVER