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

Division of Quality Surveillance Assessment
Inspection Assessment Branch
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April 1, 2015

Regis Rodrigues Samama
Industrial Director
Caq-Casa Da Quimica Ind. E Comercio Ltda
Rua Alvares Cabral,
693-Vila Conceicao CEP: 09981-030
Diadema-Sao Paulo, Brazil

Reference FEI 3003776921
Reference inspection date (s): November 10 – 14, 2014
Establishment Locale: Diadema-Sao Paulo, Brazil

Dear Mr. Samama:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at the above address or number.

Sincerely,

Concepcion Cruz
Branch Chief (Acting)
Inspection Assessment Branch

Enclosure: EIR

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SUMMARY

This initial, preannounced drug Good Manufacturing Practice (GMP) inspection of an active pharmaceutical ingredient (API) manufacturer was requested by the International Operations Group and CDER's EES inspection request. The FACTS assignment number for this inspection is 11455743 and OP ID number is 7539850. Compliance program 7356.002F (Active Pharmaceutical Ingredient Process Inspection) provided inspectional guidance along with ICH Q7 (Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients). Profile class CSN (Non-sterile API by chemical synthesis) was covered during this inspection.

The firm had not been inspected by the agency prior to this current inspection. The firm manufactures inorganic salts used as pharmaceutical API including Potassium Nitrate and Sodium Phosphate dibasic. The firm does not currently ship products to the US. This current inspection provided cGMP coverage for Potassium Nitrate API under the Quality, Facilities and Equipment, Materials, Production, Packaging, Laboratory Control and Labeling Systems.

At the conclusion of this current inspection, the inspection was classified NAI and no FDA 483 was issued. No refusal was encountered and no sample was collected during this inspection.