DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Bethesda MD 20892

May 2, 1990

Our Reference Nos.: 89-0515 & 89-0730

Patrick A. Roche, Ph.D.
Ortho Diagnostic Systems Inc.
U.S. Highway 202
Raritan, NJ 08869

Dear Dr. Roche:

Enclosed is a product license which authorizes Ortho Diagnostic Systems Inc., U.S. License No. 156, to manufacture and ship for sale, barter or exchange in interstate and foreign commerce Hepatitis C Virus Encoded Antigen. The product is to be used in an in vitro qualitative enzyme-linked immunosorbent assay for the detection of antibody to Hepatitis C Virus in human serum or plasma.

Under this license, you are authorized to manufacture Hepatitis C Virus Encoded Antigen utilizing Hepatitis C Virus Encoded Antigen (For Further Manufacturing Use) (Recombinant c100-3), manufactured by Chiron Corporation, Emeryville, California, U.S. License No. 1106, under a shared manufacturing arrangement.

You are requested to submit samples of each future master lot of the product together with protocols consisting of a summary of essential manufacturing data inclusive of all applicable test results. No master lots of the product shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research.

The expiration date of the Hepatitis C Virus Encoded Antigen is 12 months when stored at 2-8°C.

Any lot of Hepatitis C Virus Encoded Antigen found to fall outside of the approved specifications for the product, including expiration dating periods, should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of the Hepatitis C Virus Encoded Antigen should be submitted to the Office of Compliance, Center for Biologics Evaluations and Research, HFB-120.

Your establishment license application is also amended to include facilities and equipment for the production of the Hepatitis C Virus Encoded Antigen as described in your establishment amendment submission, Reference No. 89-0730.

If you wish to prepare or label the licensed product or any of the ancillary components of the test kit other than as specified in your approved license application, it will be necessary for you to submit an amendment to either your product or establishment application for review and approval prior to implementation.

Please submit three (3) copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

In addition, we request that advertising and promotional labeling be submitted for review and approval prior to the initial publication of any advertisement and prior to the initial dissemination of any promotional labeling. All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

Please acknowledge receipt of the enclosed license to the Director, Division of Product Certification, HFB-240, Center for Biologics Evaluation and Research.

Sincerely yours,

GRO-C

for Paul D. Parkman, M.D.
Director
Center for Biologics
Evaluation and Research

Enclosure