ANDA 74-881

July 28, 2000

Cook Imaging Corporation
Attention: Jennifer A. Walls
927 South Curry Pike
P.O. Box 3068
Bloomington, IN 47402

Dear Madam:

This is in reference to your abbreviated new drug application dated March 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Iopamidol-200 [Iopamidol Injection USP, 200 mgI/mL (41%)], Iopamidol-250 [Iopamidol Injection USP, 250 mgI/mL (51%)], Iopamidol-300 [Iopamidol Injection USP, 300 mgI/mL (61%)] and Iopamidol-370 [Iopamidol Injection USP, 370 mgI/mL (76%)].

Reference is also made to your amendments dated May 15, July 24 and July 25, 2000.

We have completed the review of this abbreviated application and have concluded that each drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Iopamidol-200, Iopamidol-250, Iopamidol-300 and Iopamidol-370 to be bioequivalent and, therefore, therapeutically equivalent to the listed drugs [Isovue®-200 (iopamidol injection USP, 41%), Isovue®-250 (iopamidol injection USP, 51%), Isovue®-300 (iopamidol injection USP, 61%)and Isovue®-370 (iopamidol injection USP, 76%), respectively, of Bracco Diagnostics, Inc.].

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98.

The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research