

Act 33
Section 5
Rule _____
Publ. _____
Avail. 4-30-02



02027889

April 30, 2002

NO ACT
P.E 3-29-02
132-02354

RESPONSE OF THE OFFICE OF INTERNATIONAL CORPORATE FINANCE
DIVISION OF CORPORATION FINANCE

Re: Chugai Pharmaceutical Co., Ltd. ("Chugai")
Incoming letter dated March 29, 2002

Based on the facts presented, and noting that shareholders ("Chugai shareholders") of Chugai common stock will receive the Japanese Disclosure Documents and the Information Statement (each as defined in your letter) containing information substantially similar to that required in a proxy or information statement complying with the requirements of Regulation 14A or 14C under the Securities Exchange Act of 1934 ("Exchange Act"), and that a registration statement on Form 10 under the Exchange Act with respect to the common stock ("Gen-Probe shares") of Gen-Probe Incorporated ("Gen-Probe") will be filed with the Commission and effective before the Distribution (as defined in your letter), the Division will not recommend enforcement action to the Commission if Chugai, in reliance on your opinion as counsel that registration is not required, distributes the Gen-Probe shares in accordance with the Distribution without registration under the Securities Act of 1933 ("Securities Act").

We are also of the view that the Gen-Probe shares received by Chugai shareholders in accordance with the Distribution would not be "restricted securities" within the meaning of Rule 144(a)(3) under the Securities Act. However, sales of Gen-Probe shares by Gen-Probe's affiliates would be subject to Securities Act Rule 144, except for the holding period requirement, absent registration or another appropriate exemption.

Finally, while not necessarily agreeing with your analysis in this regard, the Division will not recommend enforcement action to the Commission if an independent agent sells Gen-Probe shares without registration under the Securities Act in order to provide cash for the elimination of fractional share interests in Gen-Probe shares that otherwise would have been distributed in the Distribution.

These positions are based on the representations made to the Division in your letter. Any different facts or conditions might require the Division to reach different conclusions. Furthermore, the responses regarding registration under the Securities Act express the Division's positions on enforcement action only and do not express any legal conclusions on the questions presented.

Sincerely,

Mark W. Green
Mark W. Green
Senior Special Counsel

PROCESSED

MAY 22 2002

Ⓟ THOMSON
FINANCIAL

1172626



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

April 30, 2002

Mr. James Modlin
Hughes Hubbard & Reed LLP
One Battery Park Plaza
New York, New York 10004

Re: Chugai Pharmaceutical Co., Ltd.

Dear Mr. Modlin:

In regard to your letter of March 29, 2002 our response thereto is attached to the enclosed photocopy of your correspondence. By doing this, we avoid having to recite or summarize the facts set forth in your letter.

Sincerely,

A handwritten signature in dark ink, appearing to read "Paul M. Dudek".

Paul M. Dudek
Chief
Office of International
Corporate Finance

March 29, 2002

Paul Dudek, Esq.
Chief
Office of International Corporate Finance
Division of Corporation Finance
Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, D.C. 20549

Re: Proposed Distribution of Shares in Gen-Probe
Incorporated by Chugai Pharmaceutical Co., Ltd.

Dear Mr. Dudek:

This letter is being submitted by Hughes Hubbard & Reed LLP, as special United States counsel to Chugai Pharmaceutical Co., Ltd., a company incorporated under the laws of Japan ("Chugai"), in connection with the proposed distribution (the "Distribution") by Chugai of all outstanding shares of common stock par value \$.0001 per share ("Gen-Probe Shares") of Gen-Probe Incorporated, a company incorporated under the laws of Delaware ("Gen-Probe"), other than shares of Gen-Probe, if any, held by Gen-Probe employees, directors or consultants who received such shares pursuant to the exercise of stock options granted under Gen-Probe's 2000 Equity Participation Plan.¹ On the date hereof, Gen-Probe is an indirect wholly-owned subsidiary of Chugai. The Distribution will be made to holders (the "Chugai Shareholders") of Chugai's outstanding common stock (the "Chugai Shares") on the record date for the Distribution (the "Record Date") on a pro rata basis as described below.

I. No Action Request

On behalf of Chugai and Gen-Probe, we respectfully request that the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") (i) either (x) concur in our opinion that the proposed Distribution does not constitute a "sale" or other "disposition for

¹ Gen-Probe has established an equity participation plan pursuant to which it has issued options to employees, directors and consultants to acquire approximately 8.40% of the Gen-Probe Shares as of December 31, 2001 on a fully diluted basis. Of these, options to purchase approximately 2.20% of Gen-Probe's shares (on a fully diluted basis) were exercisable as of December 31, 2001. None of these options has been exercised as of the date hereof.

value" for purposes of the Securities Act of 1933, as amended (the "Securities Act"), or (y) confirm that the Staff will not recommend enforcement action to the Commission if the proposed Distribution to the Chugai Shareholders of Gen-Probe Shares is effected in the manner described herein without registration under the Securities Act, (ii) confirm our view that the Gen-Probe Shares received by the Chugai Shareholders will not be deemed to be "restricted securities" within the meaning of Rule 144 (a)(3) of the Securities Act and (iii) either (x) concur in our opinion that the aggregation and sale of fractional Gen-Probe Shares ("Fractional Gen-Probe Shares") as provided herein does not require registration under the Securities Act or (y) confirm that the Staff will not recommend enforcement action to the Commission if Fractional Gen-Probe Shares are aggregated and sold without registration under the Securities Act as provided herein.

As discussed in Section IV below, we are of the opinion that the Distribution does not constitute an "offer to sell" or "sale" of securities within the meaning of Section 2(a)(3) of the Securities Act, and that consequently registration of the Gen-Probe Shares is not required. As discussed in more detail in Section IV below, our opinion is not affected by the fact that Chugai is engaging in a business combination within the same time frame as the Distribution, or that Chugai Shareholders are voting on the business combination and on a reduction in Chugai's capital and/or legal reserves (the "Capital Reduction") necessary to effect the Distribution and a concurrent cash distribution. While we are submitting this no-action request because the spin-off of a United States subsidiary by a foreign parent is not covered by Staff Legal Bulletin No. 4 (September 16, 1997) ("Bulletin No. 4"), we believe that prior Staff no-action letters support our opinion that no registration is required.

We have consulted with Latham & Watkins, special counsel to Gen-Probe, in connection with this request and they have advised us that they concur in the conclusions and opinions expressed herein.

II. Background of Distribution

Chugai's primary business is the development, manufacture and marketing of prescription pharmaceuticals. Gen-Probe is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human disease (the "Clinical Diagnostic Business"). Nucleic acid probe-based products use probes that specifically bind to segments of DNA or RNA known to be unique to target organisms to identify whether the organism is present in the sample. To date, Gen-Probe has received FDA approvals for more than 40 products that detect a wide variety of infectious microorganisms.

The Chugai Shares are listed on the Tokyo, Nagoya, Osaka and Fukuoka Stock Exchanges (collectively, the "Japanese Exchanges"). As of September 30, 2001 (the most recent date on which Chugai's shareholders' registry was updated)², approximately 12.46% of

² In accordance with Chugai's articles of incorporation, Chugai updates its shareholders' registry every six months, as of September 30 and March 31 of each year.

outstanding Chugai shares were held by 104 registered shareholders with U.S. addresses as reflected on Chugai's shareholders' registry.

In its fiscal year ended March 31, 2001, Chugai had consolidated revenues of approximately \$1.637 billion. Gen-Probe generated approximately \$120 million, or 7.3%, of these revenues.

Gen-Probe was acquired by Chugai in 1989 through a merger of Gen-Probe with a wholly-owned subsidiary of Chugai. Gen-Probe has been an indirect wholly-owned subsidiary of Chugai at all times since the merger.

On the date hereof, Chugai is the beneficial owner of all outstanding Gen-Probe Shares through its direct, wholly-owned subsidiary, Chugai Pharma U.S.A., Inc. ("CPUSA").³ On or prior to the date of the proposed Distribution, CPUSA will be merged with Gen-Probe. As a result of the merger, immediately prior to the Distribution Chugai will directly hold the Gen-Probe Shares. In addition, prior to the Distribution, the Gen-Probe Shares may be split so that the number of Gen-Probe Shares held by Chugai corresponds with the distribution ratio of the spin-off.

On December 10, 2001, Chugai entered into an agreement with Roche Pharmholding B.V. ("Roche"), an indirect Dutch subsidiary of Roche Holding Ltd. ("Roche Holding"), a publicly traded Swiss corporation, whereby Roche will acquire a 50.1% interest in Chugai through a series of transactions (the "Chugai-Roche Transactions"). First, Roche will launch a tender offer for approximately 10% of Chugai Shares (the "Tender Offer"). The Tender Offer will commence after the Record Date for the Distribution. The purchase of Chugai Shares in the Tender Offer will be followed by the merger (the "Merger") of Nippon Roche (Kabushiki Kaisha), a wholly owned Japanese subsidiary of Roche, with and into Chugai, with Chugai surviving. If the shares obtained by Roche in the Tender Offer and as consideration for the Merger do not exceed 50.1% of the then-outstanding Chugai Shares, Chugai will sell additional shares to Roche (immediately prior to the Merger), such that Roche will own 50.1% of the Chugai Shares following the Merger (the "Share Issuance").

The sequence and approximate dates of the steps of the Distribution and Chugai-Roche Transactions are as follows:

<u>Event</u>	<u>Approximate Date</u>
1. Record Date of Distribution	July 31, 2002
2. Commencement of Tender Offer	August 7, 2002

³ Between the date hereof and the Record Date, additional shares of Gen-Probe common stock may be issued upon exercise of options granted under the 2000 Equity Participation Plan.

<u>Event</u>	<u>Approximate Date</u>
3. Effective date of Distribution (the " <u>Distribution Date</u> ")	September 8, 2002
4. Closing of Tender Offer	September 9, 2002
5. Share Issuance	September 28, 2002
6. Closing of Merger	October 1, 2002

Because the acquisition by Roche of Chugai Shares in the Chugai-Roche Transactions will be consummated after the Record Date, Roche will not receive Gen-Probe Shares in the Distribution.

The Merger and Share Issuance must be approved by Chugai's shareholders. Accordingly, Chugai expects to submit the Merger and Share Issuance for shareholder approval at its annual meeting of shareholders scheduled to be held on June 27, 2002 (the "Annual Meeting"). Chugai also will seek shareholder approval of the Capital Reduction at the Annual Meeting (as more fully described below).

Following the Chugai-Roche Transactions, Chugai's common stock will continue to be listed and traded on the Japanese Exchanges. Chugai Shareholders will continue to hold the same Chugai Shares following the Merger, and will not exchange their shares or receive new securities in the Merger. There will be no reclassification of, or other change in the terms, rights and preferences of the Chugai Shares.

Gen-Probe competes in the Clinical Diagnostic Business against certain U.S. affiliates of Roche Holding. Because affiliates of Roche Holding also have a substantial presence in the Clinical Diagnostic Business in the United States, Chugai and Roche have concluded that Gen-Probe would need to be divested prior to Roche's acquiring control of Chugai in order to avoid a potentially protracted and burdensome investigation by the Federal Trade Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, the outcome of which would be inherently uncertain.

Following the Distribution, Chugai and Gen-Probe will continue to operate as separate companies, and neither company will own any shares of capital stock of the other. In addition, there will be no overlap between the officers and directors of Gen-Probe, on the one hand, and the officers and directors of Chugai, on the other hand.

III. The Distribution

The Distribution will be accomplished under Japanese law through a reduction in Chugai's capital and/or legal reserves (i.e., capital reserves and profit reserves). A portion of Chugai's capital and/or legal reserves will be returned to Chugai Shareholders through the Distribution of Gen-Probe Shares. Another portion of such capital and/or legal reserves will be returned as a cash distribution (the "Cash Distribution"). Certain withholding taxes under

Japanese law arising in respect of the Capital Reduction will be withheld from the Cash Distribution.

Japanese law requires that reductions in a corporation's capital and/or legal reserves (such as the Capital Reduction) be approved by the corporation's shareholders. Accordingly, Chugai intends to seek shareholder approval of the Capital Reduction.

Prior to the Annual Meeting, information conforming to the requirements of Japanese law will be disseminated regarding Chugai, Gen-Probe and the Distribution. Such information will be contained in a convocation notice and proxy statement for the Annual Meeting (collectively, the "Japanese Disclosure Documents").

Chugai Shareholders also will receive an Information Statement before the Annual Meeting (the "Information Statement"). The Information Statement will be drafted so that, together with the Japanese Disclosure Documents, it will contain information substantially similar to the information that would be made available to shareholders in a proxy or information statement concerning Gen-Probe and the Distribution complying with Schedules 14A or 14C under the Securities Exchange Act of 1934, as amended (the "Exchange Act").⁴ Chugai will seek to ensure that all registered shareholders with U.S. addresses and all U.S. shareholders holding Chugai Shares through custody accounts with registered nominees will receive English-language versions of the Japanese Disclosure Documents and Information Statement.

Gen-Probe will file a Registration Statement on Form 10 relating to the Gen-Probe Shares with the Commission, which will become effective prior to the consummation of the Distribution.

The result of the proposed Distribution will be that all outstanding shares of Gen-Probe common stock other than shares issued to Gen-Probe employees, directors or consultants upon exercise of stock options issued pursuant to Gen-Probe's 2000 Equity Participation Plan will be owned immediately after the Distribution directly and in the same relative proportion by the same shareholders who own the Chugai Shares on the Record Date. Such shareholders will thus be treated equally in the Distribution, and will receive Gen-Probe Shares in the same proportion as their ownership of Chugai Shares on the Record Date. The Distribution will not, in and of itself, change the interests of these Chugai Shareholders in the assets of Gen-Probe. These Chugai Shareholders will have the same proportionate interest in the same aggregate assets immediately before and after the Distribution, except that immediately following the Distribution, these shareholders will hold their interests in the Gen-Probe Shares directly, rather than continuing to hold their interests in Gen-Probe through Chugai.

No consideration will be payable by the Chugai Shareholders in connection with the Distribution. The Distribution is not part of the consideration for the Merger. The

⁴ As a foreign private issuer, Chugai is not subject to U.S. proxy rules and, consequently, Chugai will not file the Japanese Disclosure Documents and Information Statement with the Commission.

Distribution is conditioned on shareholder approval of the Merger, and on the satisfaction or waiver of all other conditions (other than the completion of the Distribution) to the consummation of the Merger.

In connection with the Distribution, application will be made to have the Gen-Probe Shares listed on the New York Stock Exchange, the Nasdaq National Market or American Stock Exchange.

IV. Section 2(a)(3) of the Securities Act

It is our opinion that the Distribution does not constitute an "offer to sell" or "sale" of securities within the meaning of Section 2(a)(3) of the Securities Act and, consequently, that registration of the Gen-Probe Shares is not required.

Bulletin No. 4 and a series of no-action letters involving spin-offs confirm that registration of the shares being distributed in the spin-off is not required where: (1) the parent shareholders do not provide consideration for the spun-off shares; (2) the spin-off is pro rata to the parent shareholders; (3) the parent provides adequate information about the spin-off and the spun-off company to its shareholders and to the trading markets; (4) the parent has a valid business purpose for the spin-off; and (5) the spun-off shares are not "restricted securities" or if the parent spins-off "restricted securities," it has held those securities for at least two years (unless it formed the subsidiary being spun-off). See Bulletin No. 4; Trelleborg AB (available Apr. 26, 1999) ("Trelleborg"); AB Electrolux (available Apr. 28, 1997) ("Electrolux"); Hanson II (available Jan. 22, 1997) ("Hanson II"); Ralcorp Holdings, Inc. (available Dec. 27, 1996) ("Ralcorp"); E.W. Scripps (available July 3, 1996) ("Scripps"); Envoy Corporation (available Feb. 16, 1995) ("Envoy"); English China Clays (available Sept. 1, 1994) ("English China Clays"); AMAX Inc. (available Aug. 27, 1993) ("AMAX"); Grasso Corporation (available Aug. 20, 1993) ("Grasso"); Marriott Corporation (available Mar. 19, 1993) ("Marriott"); Asea AB (available Apr. 25, 1991) ("Asea"); BAT Industries plc (available July 5, 1990) ("B.A.T"); and Summit Energy (available Mar. 29, 1988) ("Summit Energy").

1. Consideration for Spun-Off Shares.

No consideration will be payable by the Chugai Shareholders in connection with the Distribution. The Distribution is in the form of a reduction in Chugai's capital and/or legal reserves, which will be accomplished in part through the distribution of all of the shares of common stock of Gen-Probe held by Chugai to the Chugai Shareholders on a pro rata basis.

2. Pro-Rata Distribution.

The Distribution will be pro rata to Chugai Shareholders on the Record Date. Following the Distribution, the distributed Gen-Probe Shares will be owned directly and in the same proportion (other than to the extent Fractional Gen-Probe Shares are cashed-out) by the same Chugai Shareholders who owned Chugai Shares on the Record Date. Each Chugai Shareholder on the Record Date will be treated the same way as every other Chugai Shareholder on the Record Date. These shareholders will hold an interest in Gen-Probe directly rather than through Chugai, and will have the same proportionate interest in the same Gen-Probe assets immediately before and after the Distribution.

The Tender Offer will not affect the pro rata nature of the Distribution because the right of Chugai Shareholders to receive shares in the Distribution will vest on the Record Date, before any shares are purchased in the Tender Offer. Chugai Shareholders who own Chugai Shares on the Record Date and tender their shares in the Tender Offer (or sell their shares on the open market) will receive Gen-Probe Shares in the Distribution and be treated no differently than shareholders who continue to hold their Chugai Shares.

Furthermore, the Tender Offer and other elements of the Chugai-Roche Transaction will be consummated after the Distribution Date and will not affect the share ownership of Chugai between the Record Date and Distribution Date. The only changes in Chugai's shareholders between the Record Date and Distribution Date will be through normal trading of Chugai Shares. The fact that the Chugai-Roche Transaction is being consummated after the Distribution Date also means that there will be no resulting change in Chugai's assets or business until the Distribution is complete.

That the record date of a spin-off is the appropriate date to determine whether the spin-off is pro rata is confirmed in McKesson Corporation (available Sept. 23, 1994) ("McKesson"), and Ramada Incorporated (available May 3, 1989) ("Ramada"), each involving a parent that proposed to spin-off a subsidiary to its shareholders in connection with the acquisition of the parent by a third-party through a tender offer and merger. In both cases the Staff took no-action positions even where the consummation of the tender offer and merger involving the parent occurred *between* the record date and distribution date of the spin-off. Implicit in these no-action positions is the view that the record date of the spin-off is the proper date for determining whether a spin-off is pro rata. Changes in share ownership (or the business and assets) of the parent in the period between the record and distribution dates of the spin-off as a result of the concurrent transactions were not relevant because all the shareholders on the record date were treated equally.

Our situation is more favorable than either McKesson or Ramada where the tender offer and related merger closed before the distribution date of the spin-off. In our situation, both the Record Date and the Distribution Date will occur prior to the completion of the Tender Offer and the Merger. There will be no changes in Chugai's shareholdings or assets or business resulting from the Chugai-Roche Transaction until the Distribution is complete. Thus our situation falls well within McKesson and Ramada and presents fewer concerns relating to the requirement that the Distribution be pro rata than the situations in McKesson and Ramada.

Some stock options granted under Gen-Probe's 2000 Equity Participation Plan may be exercised between the Record Date and Distribution Date, but this does not change our view that the Distribution will be pro rata to Chugai Shareholders on the Record Date as the relative interest of such Chugai Shareholders in the Gen-Probe Shares will not change. The only effect of any exercise of such options will be dilution of the interest of such Chugai Shareholders in the Gen-Probe Shares, which dilution would take place whether or not the Distribution occurs.

3. Valid Business Purpose.

The Staff has looked to the economic substance of transactions rather than to their form. By doing so, the Staff has not viewed transactions such as the Distribution as dispositions

of securities for value, but rather as a means of facilitating a policy decision of the distributing entity based on valid business reasons. See, e.g., Trelleborg; Hanson II; Ralcorp; Scripps; Envoy; Grasso; AMAX; English China Clays; Asea; and B.A.T.

The Distribution is unlike the situations presented in *SEC v. Datronics Engineers, Inc.*, 490 F.2d 250 (4th Cir. 1973) ("Datronics"), and *SEC v. Harwyn Industries Corp.*, 326 F. Supp. 943 (S.D.N.Y. 1971) ("Harwyn"), in which corporations used spin-offs without any valid business purpose to create public markets in their securities without registration of the shares. In both *Datronics* and *Harwyn*, the spin-offs were accomplished without dissemination of adequate information to either the marketplace or the shareholder-recipients. The courts liberally construed the words "for value" under Section 2(a)(3) in *Datronics* and *Harwyn* in order to prevent violations of the "spirit and purpose of the registration requirements." *Harwyn*, 326 F. Supp. at 954.

The policy concerns that led to the decisions in *Datronics* and *Harwyn* and the position of the Commission expressed in Securities Act Release No. 4982 (July 2, 1969) are not present in the Distribution. The Distribution is motivated by valid business purposes rather than by a desire to evade the registration requirements of the securities laws.

As discussed in Section II above, the Distribution is required to facilitate the Chugai-Roché Transactions which otherwise may be subject to close scrutiny by the U.S. Federal Trade Commission because of antitrust concerns. Based on this reason, there is clearly neither a desire nor an intention to evade the requirements of the United States securities laws, and we believe that the proposed Distribution satisfies the valid business purpose test.

4. Adequate Information.

Bulletin No. 4 does not address the situation where a non-reporting foreign company spins-off a non-reporting U.S. subsidiary that registers its shares under the Exchange Act. However, in footnote 5, the Staff refers to five instances of a non-reporting U.S. parent that desires to spin-off a non-reporting subsidiary. In those cases, the Staff took the view that the parent provides adequate information if it provides its shareholders with an Information Statement that substantially complies with Regulation 14A or 14C.⁵

Although Chugai is not a reporting company under the Exchange Act, Gen-Probe will register its securities under the Exchange Act prior to the consummation of the Distribution.

As required by Japanese law, Chugai Shareholders and the marketplace will receive extensive information about the Distribution through the Japanese Disclosure Documents

⁵ The footnote also notes that the Staff required limitations on the ability of holders to transfer the spin-off securities until the spin-off entity registers them under the Exchange Act. Since the Gen-Probe Shares will be registered under the Exchange Act at the time of the Distribution, this limitation is inapplicable.

and the Information Statement. Together, these documents will contain a description of the Distribution, a description of Gen-Probe's business activities and financial information regarding Gen-Probe.⁶

The Japanese Disclosure Documents together with the Information Statement will contain information substantially similar to the information which would be made available to shareholders in a proxy or information statement concerning Gen-Probe and the Distribution complying with Schedule 14A or 14C under the Exchange Act.

With respect to ongoing reporting, Gen-Probe will become subject to the reporting requirements under the Exchange Act and will be obligated to file periodic reports with the Commission accordingly.

Consequently, it is our opinion that the information regarding the Distribution and Gen-Probe being provided to the Chugai Shareholders will meet the adequate information requirement of Bulletin No. 4 and the Staff's no-action letters.

5. "Restricted Securities."

The Staff has taken the position in Bulletin No. 4 that a parent company may spin-off securities either (i) which are not "restricted securities" as defined in Rule 144(a)(3) under the Securities Act or (ii) which the parent has held for at least two years (unless the parent formed the subsidiary being spun-off rather than acquiring the business from a third party) and where the conditions in paragraphs (1) through (4) above are met.⁷ At the time of the Distribution, Chugai will have owned the Gen-Probe Shares since 1989, either directly or through a holding company.⁸

⁶ All financial information with respect to Chugai will be presented in accordance with Japanese generally accepted accounting practices. All financial information with respect to Gen-Probe will be presented in accordance with United States generally accepted accounting practices.

⁷ The possible split of the Gen-Probe Shares to correspond to the spin-off ratio should not affect the calculation of the holding period for the Gen-Probe Shares. Such a step is common in spin-offs, and the Staff has in the past given no-action relief for spin-offs where a pre-distribution stock split occurred. See, e.g., American Brands, Inc. (available Mar. 12, 1997); Sprint Corporation (available Feb. 9, 1996); St. George Minerals, Inc. (available June 12, 1990); Culbro Corporation (available Nov. 28, 1988); American Pacesetter (available May 2, 1988) ("American Pacesetter"); and Yarway Corporation (available Dec. 17, 1984).

⁸ Prior to the Distribution, Gen-Probe's Board of Directors may adopt a stockholder rights plan. If a stockholder rights plan were to be adopted, it would be adopted regardless of the outcome of the vote and separate and apart from whether or not the Merger and associated transactions are consummated. The Gen-Probe Shares would consequently include certain associated rights attached thereto (the "Rights") pursuant to a rights agreement to be entered into between Gen-Probe and a rights agent to be selected. The Rights would not be exercisable or transferable apart from the Gen-Probe Shares

6. Proximity to Merger.

The fact that the Distribution is occurring within the same time frame as the Merger does not change our opinion that registration of the Distribution is not required.

The Staff repeatedly has granted no-action requests in cases where a spin-off distribution of a subsidiary's shares is made to the parent's shareholders concurrently with a business combination involving the parent, including cases where shareholders are asked to vote concurrently on the business combination and the spin-off. See Ralcorp; Scripps; Envoy; Grasso; and Summit Energy.

For example, in Grasso the parent corporation proposed to spin-off a subsidiary immediately prior to a business combination with another company in which the shareholders of the other company would own 55% of the parent company upon completion of the business combination. As in the present case, the shareholders of the parent were to retain a minority interest in the parent following the business combination, and the shares of the parent would continue to be publicly traded. Both the business combination transaction and the spin-off were being submitted to a vote of the parent's shareholders. The spin-off and the business combination were each conditioned on consummation of the other.

Summit Energy presents a similar case. There, the spin-off was to occur prior to the issuance by the parent of 70% of its common stock as consideration for the acquisition by the parent of a third party, and the parent requested shareholder approval for the spin-off and the acquisition. In Envoy, the parent corporation proposed to contribute its health care and governmental benefit electronic transaction processing business to a subsidiary and distribute its shares of the subsidiary's common stock to its shareholders immediately prior to the merger of the parent corporation with and into the acquiror. As in Grasso, both the acquisition and the spin-off were to be submitted to a vote of the parent's shareholders, and the spin-off and the acquisition were each conditioned on consummation of the other.

(Footnote continued from previous page)

unless and until certain events occur. If certain events occur relating to the acquisition by an "acquiring person" of Gen-Probe Shares, the Rights would entitle holders (other than the acquiring person) to purchase Gen-Probe Shares at a discount or, in the event of a merger or other combination of Gen-Probe with an acquiring person, the Rights would entitle holders (other than the acquiring person) to purchase common stock of the acquiring person or Gen-Probe Shares, if applicable, at a discount. The specific terms of the Rights will be determined by the Board of Directors of Gen-Probe prior to the date on which the Information Statement is distributed to Chugai Shareholders and will be described in the Information Statement. We note that the Staff has issued no-action letters in which stock purchase rights such as the Rights were included along with the stock of the company that was being distributed in the spin-off. See, e.g., Ralcorp; and Bone Care International, Inc. (available May 31, 1996) ("Bone Care").

Moreover, that the spin-off and business combination are conditioned on shareholder approval of both transactions does not change the Staff's view in these no-action letters. The result was the same whether the shareholder vote in connection with the spin-off was required by law (Scripps), was not required by law (Envoy) or was taken where the law was unclear (Ralcorp).

Similarly, the Staff has recognized that the shares to be distributed in the spin-off will not be deemed to be consideration in the business combination in situations where a business combination and spin-off are concurrent, are subject to shareholder approval, and will not be consummated unless both are approved. See Ralcorp; Scripps; Envoy; and Grasso. The Information Statement will state that while the Gen-Probe Shares to be received in the Distribution are not consideration to be received in the Merger, the Distribution will be made only if the Merger is approved and all other conditions to the consummation of the Merger (other than the completion of the Distribution) have been satisfied or waived.

7. Rule 145.

We are also of the opinion that the Distribution should not be viewed as involving a transfer of assets or other transaction covered by Rule 145 under the Securities Act that would result in the Distribution being deemed to involve an "offer to sell" or "sale" of securities within the meaning of Section 2(a)(3) of the Securities Act by virtue of such Rule. Since its response in First Bancshares of Florida, Inc. (available Aug. 27, 1979), the Staff has repeatedly taken a no-action position with respect to spin-off transactions even when these transactions involved or required a shareholder vote on the spin-off itself. See, e.g., Trelleborg; Hanson II; Ralcorp; Scripps; U.S. Trust Corporation (available May 25, 1995); Sears, Roebuck & Co. (available Feb. 15, 1995); Emulex Corporation (available Dec. 30, 1993); AMAX; Grasso; Marriott; and B.A.T.

Bulletin No. 4 expressly recognizes that a shareholder vote will not by itself require registration under the Securities Act if a spin-off otherwise meets the Bulletin's requirements.

The Preliminary Note to Rule 145 makes it clear that the Rule was intended to provide the protections of registration under the Securities Act to persons who are making a new investment decision regarding a new or different security in connection with any of the business combinations enumerated in the Rule unless an exemption from registration is available.⁹ Through the Distribution, Chugai will distribute its share of an existing business proportionately to its existing shareholders. No new investment decision is required to be made by the existing

⁹ While the Merger is subject to shareholder approval, the shareholder vote does not relate to a transaction covered by Rule 145 because Chugai Shareholders will not exchange their shares for other securities or receive new securities in the Merger. Chugai will be the survivor in the Merger and Chugai shareholders will continue to hold the same Chugai Shares following the Merger. The terms, rights and preferences of such securities will not be altered and they will continue to be listed on the Japanese Exchanges.

Chugai Shareholders; no sale of assets to an independent third party in the sense intended in Rule 145 will take place; and no "value" under Section 2(a)(3) of the Securities Act is being given by the Chugai Shareholders for the Gen-Probe Shares. Chugai, through the Distribution, is distributing to its existing shareholders shares of Chugai's subsidiary in a pure spin-off.

The shareholders' vote on the Capital Reduction is being undertaken not because the Distribution concerns a fundamental change in the shareholders' investments, but because such a reduction in capital and/or legal reserves is required to be approved by shareholders under Japanese law.

As discussed in Part 6 above, the fact that the Distribution is occurring within the same time frame as the Merger does not change the analysis.

After the Distribution, the Gen-Probe Shares will be owned directly and in the same relative proportion by the same shareholders who own the Chugai Shares on the Record Date. Consequently, the Distribution will not, in and of itself, change the interests of the Chugai Shareholders in the assets of Gen-Probe. The spin-off shares are not consideration in the Merger. Accordingly, we are of the view that the Chugai Shareholders are not making a new investment decision, and the shareholder interests that Rule 145 was designed to protect are not affected by the Distribution.¹⁰

For the foregoing reasons, it is our opinion that the Distribution is not a "sale" of securities requiring registration under the Securities Act by virtue of Rule 145.

8. Cash Distribution

That the Cash Distribution is being declared together with the Distribution does not change our opinion. As part of the Capital Reduction, the Cash Distribution represents the pro rata return (in the form of cash) to Chugai Shareholders of a portion of their capital and/or legal reserves in Chugai. As with the Distribution, the Chugai Shareholders' claim on such capital and/or legal reserves is being converted from an indirect to a direct interest. The Staff has in the past recommended that no enforcement action be taken with respect to an unregistered spin-off occurring concurrently with an extraordinary dividend. See Zayre Corporation (available May 15, 1989).

¹⁰ The fact that Gen-Probe has issued options to employees, directors and consultants should not change the analysis, even if options are exercised prior to the Distribution. The Staff has in the past recommended that no enforcement action should be taken with respect to unregistered spin-offs by parent companies of partially-owned subsidiaries. See, e.g., Trelleborg (42.9% subsidiary); Santa Fe Energy Resources, Inc. (available July 2, 1997) (83% subsidiary); and Bone Care (97.3% subsidiary).

9. Conclusion.

Based on the discussion above and in light of prior Staff spin-off letters concerning similar transactions, we believe that the Distribution satisfies all five of the Staff's requirements relating to spin-offs as outlined in Bulletin No. 4 and the similar requirements set forth in previous no-action requirements: (1) the Chugai Shareholders will not provide consideration for the Distribution; (2) the Distribution will be pro-rata to the Chugai Shareholders; (3) a valid business purpose exists for the Distribution; (4) (a) adequate information with respect to the Distribution will be disseminated to the Chugai Shareholders through the Japanese Disclosure Documents and the Information Statement and (b) there will be adequate public information in the marketplace regarding Gen-Probe and the Gen-Probe Shares through Gen-Probe's compliance with the reporting and disclosure requirements under the Exchange Act; and (5) Chugai will have beneficially owned the Gen-Probe Shares for more than two years. It is also our opinion that the Distribution is not a transaction covered by Rule 145 notwithstanding the facts that Chugai will be engaging in a business combination in the same time frame as the distribution and Chugai's shareholders will be asked to vote on both the Merger and the Capital Reduction.

Based on the foregoing, we respectfully request on behalf of Chugai and Gen-Probe that the Staff either (i) concur in our opinion that the proposed Distribution does not constitute a "sale" or other "disposition" for "value" for purposes of the Securities Act or (ii) confirm that it will not recommend that the Commission take any enforcement action if the Distribution is effected without compliance with the registration requirements of the Securities Act.

V. Rule 144

We are also of the view that the Gen-Probe Shares that will be distributed to the Chugai Shareholders will not constitute "restricted securities" as defined in Rule 144(a)(3) under the Securities Act because the Gen-Probe Shares will be acquired by the Chugai Shareholders and would therefore have been issued to the public.¹¹ We believe, therefore, that U.S. holders of the Chugai Shares, except for affiliates of Gen-Probe, should be able to sell Gen-Probe Shares without complying with Rule 144.¹²

In Bulletin No. 4, the Staff stated that securities received by shareholders in a spin-off that meets the five conditions detailed in paragraphs (1) through (5) of Section IV above generally are not "restricted securities." Moreover, the Staff has on several occasions adopted the view that shares distributed in transactions similar to the proposed Distribution would not be

¹¹ We have been informed that there is no large shareholder of Chugai that controls Chugai such that it is essentially deciding whether Chugai proceeds with the Distribution.

¹² We recognize that any United States shareholders of Chugai who become affiliates of Gen-Probe will be subject to Rule 144 absent registration under the Securities Act or another appropriate exemption.

deemed to be restricted securities within the meaning of Rule 144(a)(3) of the Securities Act. See, e.g., Trelleborg; Ralcorp; Scripps; Envoy; English China Clays; Asea; and B.A.T.

VI. Sales of Fractional Gen-Probe Shares

Chugai Shareholders who are entitled to receive Fractional Gen-Probe Shares in the Distribution will, in lieu of receiving the Fractional Gen-Probe Shares, have their fractional shares aggregated and sold on the open market by an independent agent (the "Fractional Share Agent"), through one or more brokers selected by it, with the proceeds being distributed to such shareholders on a pro rata basis. It is our opinion that the sale of Fractional Gen-Probe Shares in the manner described herein does not require registration under the Securities Act. If the Staff concurs in our opinion that the proposed Distribution does not constitute a "sale" for purposes of the Securities Act, or determines not to recommend that enforcement action be taken by the Commission upon implementation of the Distribution in the manner described in this letter, we request that the Staff also confirm that it will not recommend that enforcement action be taken by the Commission if the Fractional Share Agent sells such Fractional Gen-Probe Shares under such circumstances without registration.

In Bulletin No. 4, the Staff stated its belief that a subsidiary need not register an independent agent's sales of fractional shares in a spin-off that meets the five conditions detailed in paragraphs (1) through (5) of Section IV and if (i) the independent agent makes the sales in the open market; (ii) the independent agent, in its sole discretion (without influence by the parent or the subsidiary), determines when, how, through which broker-dealer and at what price to make its sales; and (iii) the independent agent and the broker-dealers it uses are not affiliates of the parent or the subsidiary.

As described above, the Distribution meets the conditions detailed in paragraphs (1) through (5) of Section IV. The Fractional Share Agent will effect the necessary sales of Fractional Gen-Probe Shares on behalf of the Chugai Shareholders in the open market in such amounts and at such prices and times as it deems appropriate and through broker-dealers, who shall have been selected in its sole discretion. The Fractional Share Agent will not be an affiliate of, or subject to the control of, Chugai or Gen-Probe. The Fractional Share Agent's actions will be independent of both Chugai and Gen-Probe, and any broker-dealers selected by the Fractional Share Agent to effect sales of Fractional Gen-Probe Shares will not be affiliates of either Chugai or Gen-Probe and will not be subject to the control of either Chugai or Gen-Probe.

Based on the foregoing, we request that the Staff confirm that it will not recommend that enforcement action be taken by the Commission if the Fractional Share Agent sells Fractional Gen-Probe Shares under such circumstances without registration.

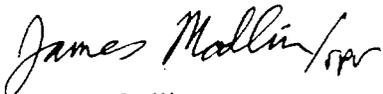
VII. Conclusion

Based on the foregoing, we respectfully request that the Staff grant each of the items of relief requested above.

In accordance with Securities Act Release No. 33-6269 (December 5, 1980), seven additional copies of this letter are enclosed. If you have any questions or there is further information that you require with respect to these matters, please contact James Modlin at

(212) 837-6817 or John J. Huber or Robert E. Burwell of Latham & Watkins, special counsel to Gen-Probe, at (202) 637-2242 and (858) 523-5408 respectively. If for any reason the Staff does not concur with the views expressed in this letter or finds itself unable to grant the relief requested hereby, we respectfully request a conference or telephone conference with the Staff before any written response to this letter is issued.

Very truly yours,



James Modlin
Hughes Hubbard & Reed LLP
One Battery Park Plaza
New York, New York 10004
Telephone (212) 837-6000

NY 612248_25