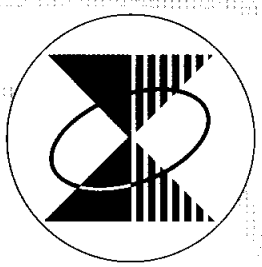
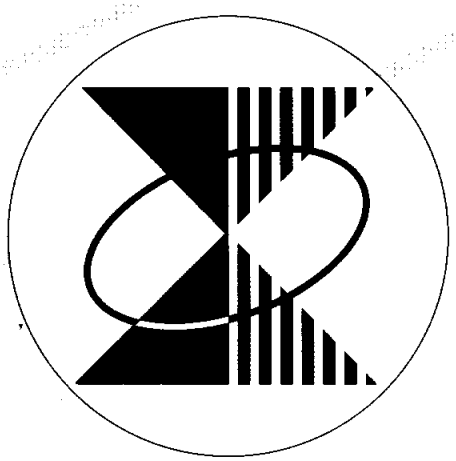
18th Annual Report

2002

Gaining Momentum





NEULAND

LABORATORIES LIMITED

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NEULAND LABORATORIES LIMITED

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION — CENTER FOR DRUG EVALUATION AND RESEARCH

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Division of Manufacturing and Product Quality
7520 Standish Place
Rockville, Maryland 20855-2737

TELEPHONE: (301) 594-0095
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APR 29 2002

Dr. D.R. Rao, Ph.D.
Chairman and Managing Director
Neuland Laboratories Limited
Pashamylaram, Isnapur, Patancheru
Medak District 502319
Andhra Pradesh State
India

Dear Dr. Rao:

We have reviewed the Establishment Inspection Report (EIR) for the inspection of your active pharmaceutical ingredient (API) manufacturing facility located in Andhra Pradesh, India by the United States Food and Drug Administration during February 11 - 12, 2002. We conclude that your firm is acceptable for the production nonsterile APIs produced by chemical synthesis.

In addition, we enclose a copy of the February 2002 establishment inspection report (EIR) which is provided to you for information purposes. The Agency is working to make its regulatory processes and activities more transparent to the regulated industry. Releasing this EIR to you is part of that effort. The copy provided to you comprises the narrative portion of the report and reflects redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. This, however, does not preclude you from requesting and possibly, obtaining any additional information under FOIA.

Please contact me at the address or telephone numbers provided above if you have any questions or concerns regarding the released information. Reference Central File (CFN) number 9617754 and Field Establishment Inventory (FEI) number 3003309323 on all correspondence to this office.

Edwin Rivera Martínez
Compliance Officer

Enclosure

A precious Certification

Neuland is poised for tomorrow. Ready to take giant strides. A company that is confident and enthusiastic to leap ahead. A company that is moving from focus and vision to mission. The mission is to deliver larger volumes to the discerning markets. On the well-known Neuland platform of quality.

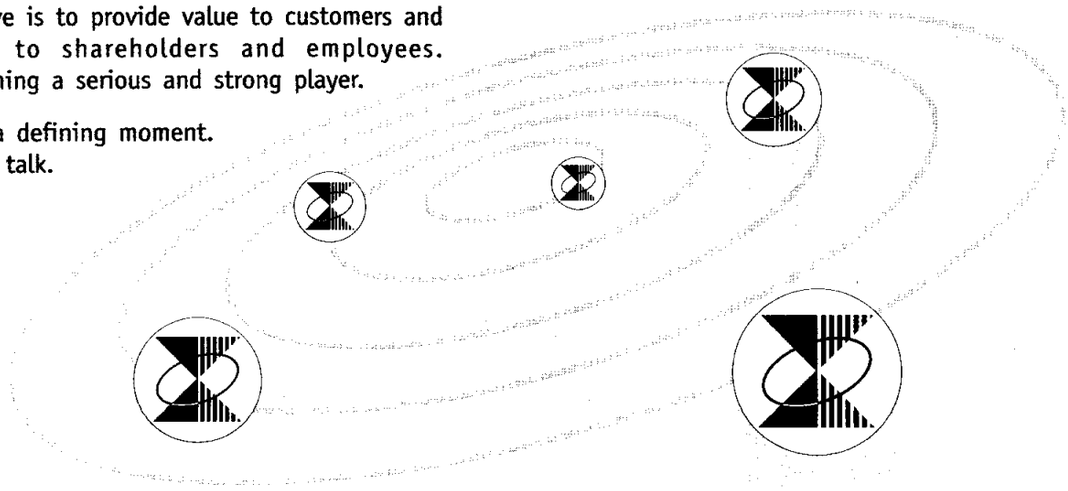
The Company can change gear because it has feet on ground. Target setting and focus is clear. Value creation has been planned well. Cautious steps in the last few years, ensured that the deliverables were as good as the customers wanted. The simple fundamental has been health industry needs the purest of products.

Neuland has ensured this momentum by putting in place the necessary infrastructure. Systems, operating procedures, validations are key drivers within the organisation. The quality *mantra* became a commitment to ethics and values. The foundation became strong. The recognition came with US FDA and European regulatory approvals and repeat orders from large customers. The reputation traveled in line with the deliveries.

Consistent performance gives confidence to make fresh commitments and offer guarantees. This paradigm shift is the result of a fresh look at the Company. Strategies have been improved and considerable work on ground has been done. Strengths have been further consolidated and roadblocks removed. The destination is clear. Mapping has been done. Milestones and landmarks for future growth identified. The delivery channels are in place, and some of the finest navigators are in command.

Today, the organisation has become leaner, younger, and is looking out for opportunities in the market and offering solutions. The objective is to provide value to customers and thereby add value to shareholders and employees. The Company is becoming a serious and strong player.

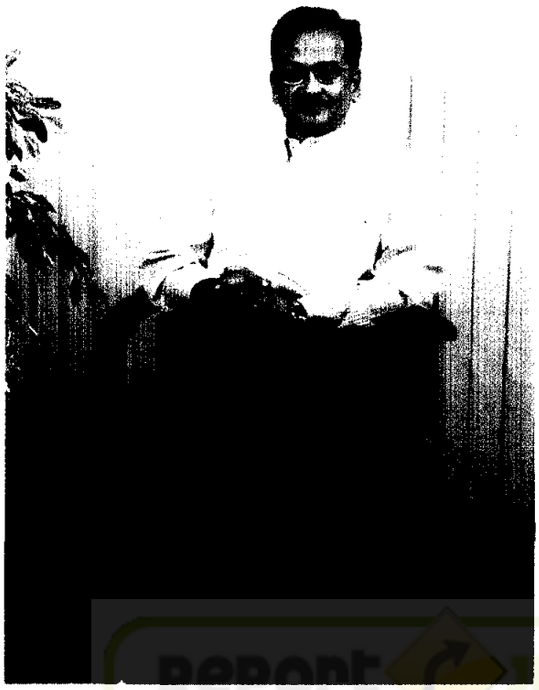
Neuland has reached a defining moment.
It is ready to walk the talk.



LETTER FROM THE CHAIRMAN & MANAGING DIRECTOR

Gaining Momentum

OVERVIEW



Dear friends,

The year was challenging for the pharma industry. Yet, Neuland's performance can be considered fair. Consequent to the September terrorist attacks, the industry had forecast acceleration. There was alround stepping up of capacities and production. The demand however remained subdued, and the prices flattened. Competitive pressures were up. The industry scenario was tough.

Despite the odds, Neuland forged ahead in 2001-02. Bulk drug production volumes were up by 16.8 per cent. Correspondingly, volume sales were up by 16.5 per cent and the turnover rose by 15.6 per cent.

The Company aggressively positioned itself in the discerning export market. Exports at Rs.55.76 crore showed a growth of 43.3 per cent over the previous year. In the process, exports constituted 55 per cent of the total turnover.

Quality conscious markets are willing to pay a premium for consistent and reliable products. Neuland has often been the beneficiary, and the demand from the global markets during the year, helped maintain aggregate margins. The operating profit improved.

The Company cashed in on FDA approval earlier received for Ranitidine Hydrochloride Form I. The Certificate of Suitability for Ranitidine Hydrochloride and Ciprofloxacin Hydrochloride helped market the products in European countries. The forward plans are to use these products as revenue drivers on the back of the regulatory approvals. The Company is working towards larger volume targets.

Two more products, Ramipril and Mirtazapine were commercialised. R & D work is now being carried out on newer initiatives and the Company hopes to scale up technologies for products like Olanzapine, Citalopram and Flecainide.

During the year, the Company's Pashamylaram plant, where Latonoprost, an innovative drug for glaucoma is being produced, was inspected by the US FDA authorities. Neuland is a contract manufacturer for the drug. The plant received the FDA approval for manufacture of non-sterile active pharmaceutical ingredient produced by chemical synthesis. This is a significant development for the Company and portends larger business and reinforces credibility.

Neuland forged strong relationships with more number of customers, and more important, newer customers were added. The strengths and recognition built over a track period gives confidence to commit the Company to become a larger player.

Going forward, the Company has its hard and software ready. De-bottlenecking has been put through at the Pashamylaram unit and both the manufacturing facilities have been upgraded to meet the current international GMP requirements of the regulated markets.

In order to meet the increased demand, additional capacities are being tied up. Intermediate products are being outsourced, releasing in-house capacities that would facilitate manufacture of finished products.

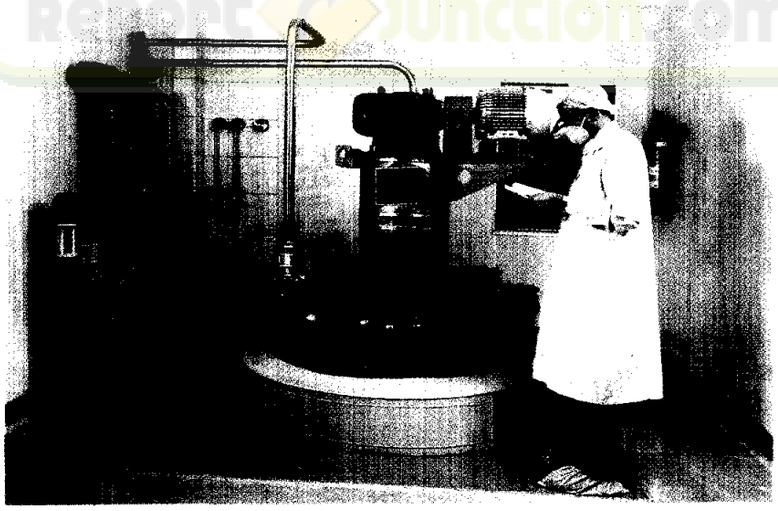
Enhanced level of activity, supervision of products being bought-out, stringent quality control on contract manufacture etc. need to be matched by increased managerial inputs. This has been ensured, with every activity being monitored by competent and dedicated professionals. Managerial strength at Neuland has been reinforced.

Neuland is gaining momentum and looks to meet newer challenges. In fact, the team has trained its sights on the market out there, and has an enthusiasm to get things done.

The stakeholders, and all those associated with the Company would see the difference. There is now a thrust that will help deliver what they want.

With warm regards,

Dr.D.R.Rao
Chairman & Managing Director



Ciprofloxacin Hydrochloride manufacture - pharma stage

Review *of* Operations

PERFORMANCE REVIEW

EXPORTS

Demand for Neuland's products was a notable feature

The year 2001-02 saw the Company creating stronger bonds with customers; adding new customers; improving exports of products with regulatory approvals; launch of high value products; indeed the marketing strength further improved. The result was a significant increase in exports to the international markets.

Demand for Neuland's products was a notable feature of the year. This excitement was all the more gratifying because the Company could start converting to cash the regulatory approvals received earlier. There were new customers for Ciprofloxacin and Ranitidine, for both of which the Company holds regulatory approvals in different markets.

REGULATORY APPROVALS

opening doors to buyers in the quality conscious markets

Neuland received Certificate of Suitability from the Council of Europe for Ciprofloxacin HCl EP. This has already opened doors to a number of buyers in the quality conscious European market. TGA approval from Australia for Ciprofloxacin is another recognition that would help tap a new market. US FDA approval for Latonoprost is another feather in the cap.

Drug Master Files (DMF) submitted to regulatory authorities are inventorised below:

In USA for FDA approval

Product	DMF # & date
Enalapril Maleate	15434 dt. 15.05.2001
Ipratropium Bromide EP	15130 dt. 06.11.2000
Itraconazole	15445 dt. 15.05.2001
Mirtazapine	16007 dt. 11.06.2002
Ofloxacin	15433 dt. 15.05.2001
Sotalol HCl USP	14951 dt. 13.07.2000

Drug Master Files has been filed for Sotalol Hydrochloride EP with the Council of Europe for Certificate of Suitability. In a few other European countries, Drug Master Files have also been filed. These are for instance, Ciprofloxacin and Mirtazapine in Denmark, Ranitidine and Ofloxacin in Greece, Sotalol in France, Terbutaline in Spain etc.

Approvals received from international regulatory authorities

Certifying Authority	Products approved	Unit
Certificate of Suitability	Ciprofloxacin Hydrochloride	Pashamylaram
Council of Europe	Ranitidine Hydrochloride Form I	Pashamyram
	Salbutamol Sulphate EP	Bonthapally
FDA, USA	Albeturol Sulphate	Bonthapally
	Ciprofloxacin Hydrochloride	Pashamylaram
	Latanoplast	Pashamylaram
	Ranitidine Hydrochride Form I	Pashamylaram
	Ranitidine Hydrochride Form II	Pashamylaram

APPROVALS ON HAND

both Certificate of Suitability from Council of Europe and FDA, USA

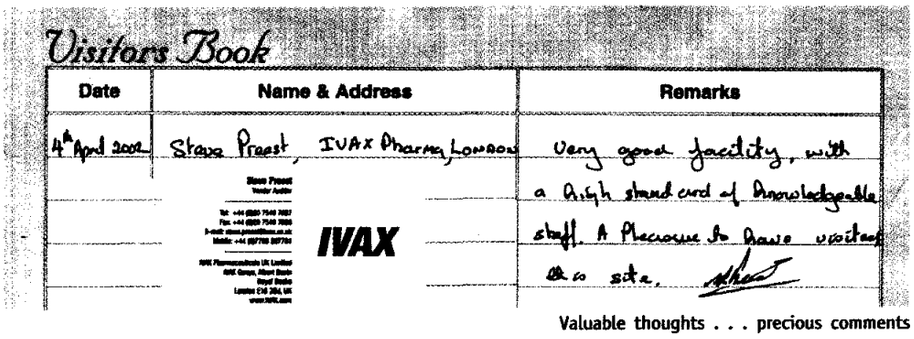
Newer products like Mirtazapine, Ramipril and Ipratropium Bromide have been added to the product portfolio, and the acceptance levels have been encouraging.

Today, the word out there is Neuland stands for quality at any cost. This basic honesty towards customers distinguishes the Company. Remarkably, both customers and competitors of Neuland have recognised this core strength.

Neuland stands for quality at any cost

A new revenue earner for the Company was contract manufacture. Although income was marginal, this is an area with tremendous potential. Incomes are expected to increase. The strengths in the market would improve, with increased presence. Neuland would have already accessed the generics markets,l and be ready to play a meaningful role in the post 2005 era, when the WTO recommendations are likely to be enforceable. In order to make it happen, Neuland has established relationships, with large organisations. These will mature into billing in the forward years.

A new revenue earner - contract manufacture



Visitors Book

Date	Name & Address	Remarks
4th April 2002	Steve Priest, IVAX Pharma, London	Very good facility, with a high standard of knowledgeable staff. A Pleasure to have visited the site.

IVAX

Valuable thoughts . . . precious comments

PERFORMANCE REVIEW

STEROIDS PROJECT
Forward plans are to become a significant player

The steroids project got underway energetically. The Technology Development Assistance of Rs.75 lakhs from the TIFAC, a Government of India sponsored organisation, is a healthy signal. Forward plans are to become a significant player in the steroids market.

ISO 9001:2000 series implemented

During the year under review, ISO 9001:2000 series was implemented. The facilities at the R & D wing as well as Quality Assurance were enhanced. New equipments were added at the Bonthapally unit. It needs to be mentioned that Neuland does far more stringent tests before the products are packed.

WORKING CAPITAL
Better realisations and quicker operating cycles improved working capital

The breakthrough for Neuland came in the form of higher exports, which not only added to operating margins, but also speeded up the collections. Better realisations and quicker operating cycles improved the working capital. The increased velocity helped drop interest costs.

Significantly, the Company saw higher business volume while maintaining the same working capital. In fact, cost of capital reduced as a proportion to the tonnage delivered.

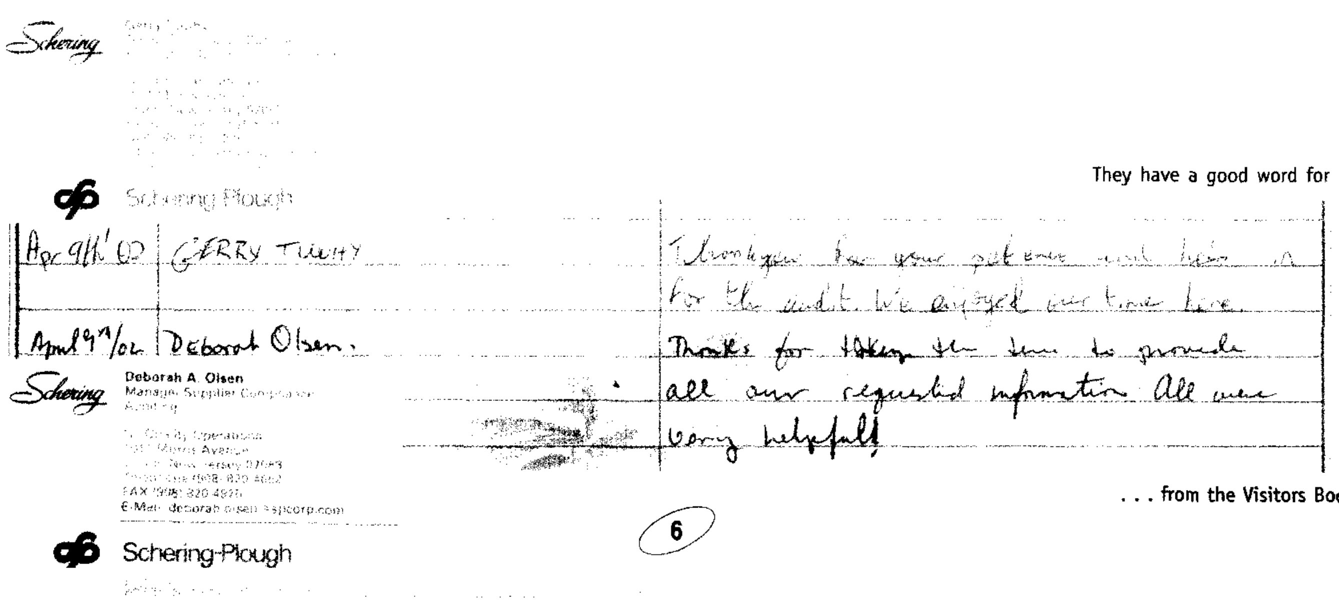
repaid part of the loans

The Company repaid part of the loans. Some high cost loans were switched with lower coupon borrowings. Additional business, over 15 per cent higher than the previous year, was achieved without increase in working capital tie-up. Smarter money management is now getting to be visible.

Positioning has improved. The year closed with optimism

The year 2001-02 actually was a launch pad for 2002-03. Neuland added strengths, reached out better and confirmed its potentialities. Positioning has improved. The year closed with optimism.

They have a good word for us



. . . from the Visitors Book

The Outlook is Exciting

focus on regulatory markets

The idea is to concentrate on regulatory markets. The Company will develop volume business and market to those who insist on quality, approvals and documentation. This will translate to dedicating entire production capacity to quality conscious customers and remaining a preferred vendor.

strategies meeting with success.

Strategies have been refined for both short and medium term for competitiveness and are being implemented. The objective is to deliver products for which the Company holds approvals. Put in perspective, the focus is on areas where the Company has the best opportunities for growth. This is meeting with success.

Ciprofloxacin is the driver

For instance, Ciprofloxacin has become the driver to the European markets. In fact, tie-up has been made with four leading generic companies in Europe. Deliveries to some of them have commenced in the new financial year.

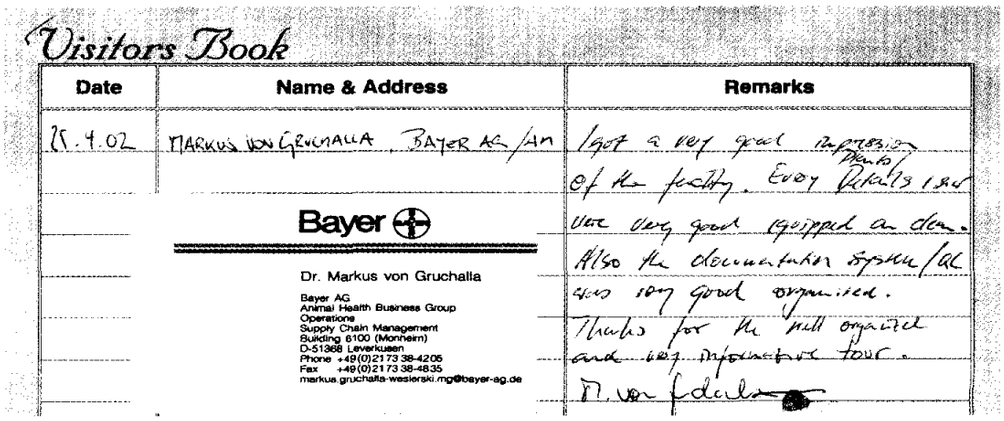
propose to outsource intermediates for global markets

Manufacturing facilities are getting better utilised. The Company will re-engineer capacities by dispensing with early stage manufacture. It is proposed to outsource intermediates, so as to release capacity for manufacture of finished products.

follows strictly the ICH guidelines

Neuland will outsource intermediates only for other global markets and for the regulatory markets will follow strictly the ICH guidelines for manufacture, packing and release of products from the Company facilities. There will be no compromise.

Every visitor, a V.I.P.



Visitors Book

Date	Name & Address	Remarks
25.4.02	MARKUS VON GRUCHALLA, BAYER AG/AM	I got a very good impression of the facility. Every detail is very good equipped an clean. Also the documentation system/QC was very good organized. Thanks for the well organized and very informative tour. M. von Gruchalla

Bayer

Dr. Markus von Gruchalla

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markus.gruchalla-wesierski.mg@bayer-ag.de

FORWARD PLANS

endeavour to generate attractive operating margin

The Company will endeavour to generate an attractive operating margin and steady earnings growth. Revenue model then is to do volume in premium markets, which by corollary protects earnings.

emphasis is on operational excellence

Neuland while building marketing strengths and launching new products will concentrate on reducing the cost structure. Productivity is being targeted by improving sourcing of raw materials, achieving higher yields and better utilisation of solvents. Emphasis is on operational excellence.

product development efforts

Neuland believes its product development efforts will help achieve long-term sustainable growth. Work on new molecules would enable making a presence in the market, as well as in process development. Currently the products being handled are Pirbuterol, Citalopram, Flecainide, Olanzipine and Fluticasone.

net liabilities would reduce

The working capital tie-up would further reduce, and it is estimated that about Rs.7 crore of the net liabilities would be reduced in the financial year 2002-03. The drive towards exports will help improve the funds flow, and further taper the cost of financing.