ANSELL LTD
Form 20-F/A
January 15, 2004

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F/A

(Mark One)

¨ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended 30 June 2003

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number **0-15850**

Ansell Limited

(Australian Company Number **004 085 330**)

(Exact name of Registrant as specified in its charter)

Ansell Limited

(Translation of Registrant s name into English)

Victoria, Australia

(Jurisdiction of incorporation or organisation)

Level 3, 678 Victoria Street, Richmond, Victoria, 3121, Australia

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
None	**None**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

Ordinary Shares

American Depositary Shares*

* Evidenced by American Depositary Receipts, each American Depositary Share representing four (4) Ordinary Shares

Securities registered or to be registered pursuant to Section 15(d) of the Act.

None

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report.

Ordinary Shares 185,706,901 (at 30 June 2003)**

** This figure includes 1,332,184 shares represented by the 333,046 American Depositary Shares outstanding on 30 June 2003.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Indicate by check mark which financial statement item the registrant has elected to follow	x Yes	¨ No
	¨ Item 17	x Item 18

EXPLANATORY NOTE REGARDING AMENDED FORM 20-F

The purpose of this amendment is to amend and restate Item 4B Business Overview Regulation and Environmental Matters Government Regulation United States.

Contents

SEC ITEM	PAGE NO
PART I	
Item 4 : Information on the Company	1
4B Business Overview	1
PART III	
Signature	3
Item 19 : Exhibits	4
Exhibit Index	4

PART I

Item 4 : Information on the Company

4B Business Overview

Regulation and Environmental Matters

Government Regulation

The products Ansell Limited manufactures are subject to regulations of varying degrees in each of the countries in which the Company markets its products. These regulations have been particularly advanced in the United States by the Safe Medical Devices Act of 1990 and in Europe, with the completion of the work required by the Single European Act of 1986 and its on-going implementation. In addition, harmonisation of regulatory requirements and reciprocity of testing procedures and data, on an international basis, has led to the adoption of an international quality management system standard, which is being implemented progressively by various regulatory authorities including the FDA and the Commission of the European Union.

Changes in existing requirements or adoption of new requirements could adversely affect Ansell Healthcare s ability to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on the business, financial condition and results of operations.

United States

In the United States, products offered through Ansell s Professional Healthcare and Personal Healthcare segments are regulated as medical devices under the Federal Food, Drug and Cosmetic Act (the FDC Act) by the FDA. We believe that all of the Company s products regulated by the FDC Act are in compliance in all material respects with the relevant sections of the FDC Act and the advice and guidance provided by the FDA. Medical device manufacturers are subject to periodic inspections and audits by the FDA for compliance with the FDA s current Quality System Regulation, which specifies good manufacturing practices (known as QSR/GMP requirements) for medical devices. The FDA has a number of compliance and enforcement procedures when deviations from QSR/GMP requirements are observed during such inspections. Which procedures are used depends upon the seriousness of the observations as well as the compliance history of the facility inspected and the company owning it.

As a general matter, the FDA often seeks to resolve observed QSR/GMP deficiencies on a voluntary basis without resorting to formal administrative enforcement action. In many cases, the FDA and the affected company enter into an agreement whereby the company retains one or more recognised, expert consultants to assist the company in achieving substantial compliance with the relevant QSR/GMP requirements and to certify that such efforts have been successful. When observed QSR/GMP deficiencies cannot be resolved through voluntary action and in a timely manner, the FDA has the option of initiating further enforcement action, including warning letters, import alerts, product bans, field corrections, seizures, recalls, injunctions, civil penalties, fines based on the equitable remedy of disgorgement, adverse publicity issued by the FDA and criminal prosecutions.

Each manufacturing operation of Ansell Healthcare has a Quality Assurance/Quality Control (QA/QC) department with its own budget. Also, we operate in a total quality environment where all participants in the manufacturing process are responsible for quality. It is the responsibility of the QA/QC department along with manufacturing to maintain the quality systems and records.

The FDA has periodically inspected most of Ansell Healthcare s manufacturing facilities, including Ansell Healthcare s overseas manufacturing facilities and has made observations on how manufacturing operations could be improved. In upgrading manufacturing facilities to address the FDA s observations and evolving technology and to otherwise comply with QSR/GMP requirements, we have and will continue to expend time, monies and efforts in the areas of product and quality control.

The FDA currently requires manufacturers intending to market a new medical examination glove, surgical glove or condom or to modify significantly a previously cleared medical examination glove, surgical glove or condom or the labelling of one of these products to obtain prior clearance. Although we typically have not experienced delays in obtaining clearance for new medical examination glove, surgical glove or condom products, there can be no assurance that we will not experience such delays for future products. An adverse determination by the FDA or a request for additional data or information could have the effect of delaying or precluding clearance and, at the same time, could materially delay or block the commencement of marketing new medical examination glove, surgical glove or condom products.

PART I

Item 4 : Information on the Company

4B Business Overview (continued)

Regulation and Environmental Matters (continued)

The FDA examines medical examination gloves, surgical gloves and condoms that are imported into the United States by randomly testing some but not all shipments for defects. If a shipment of any of these products is found to be defective, the manufacturing facility that produced the defective product will be subject to a Level 1 import alert. Under Level 1, no further shipments will be cleared for import unless tested and shown not to be defective.

A facility will be removed from Level 1 if five consecutive shipments are tested and shown not to be defective. The facility can then import shipments without prior testing but subject to possible FDA testing on a random basis. If a second shipment is found to be defective during testing while on Level 1 or in random FDA testing during the 24 months after removal from Level 1, the manufacturing facility will be placed on Level 2 import alert. On Level 2, no further shipments will be cleared for import unless tested and shown not to be defective.

A facility will be removed from Level 2 if ten consecutive shipments are tested and shown not to be defective. The facility can then import shipments without prior testing but subject to possible FDA testing on a random basis. If a second shipment is found to be defective during testing while on Level 2 or in random FDA testing during the 24 months after removal from Level 2, the manufacturing facility may be placed on Level 3 import alert. A facility on Level 3 cannot import further shipments even if they have been tested and shown not to be defective.

A facility can be removed from Level 3 only by showing FDA that the facility complies with QSR/GMP requirements based on an acceptable FDA inspection or a certification by the facility based on an independent audit by a qualified third party. After this, the facility will be placed on Level 1 detention and must seek removal from that status as described above.

Ansell s condom manufacturing facilities in Bangalore, India and Surat Thani, Thailand were placed on Level 2 detention in March 2003. The import alerts remained in effect for approximately 1 month and were lifted in April 2003. Ansell s glove manufacturing facility in Shah Alam, Malaysia was placed on Level 1 detention in October 2002. The import alert remained in effect for 3 months and was lifted on January 6, 2003. See also Item 5A Operating Results.

Labelling and promotional material for medical examination gloves, surgical gloves, and condoms are regulated by the FDA under the FDC Act and violations are subject to enforcement action as described above. Advertising for medical examination gloves, surgical gloves, and condoms is regulated by the Federal Trade Commission (FTC) under the Federal Trade Commission Act and violations are subject to enforcement action by the FTC including orders prohibiting objectionable claims, civil monetary penalties, monetary consumer redress, and orders requiring corrective advertising. We believe that the labelling and advertising of all Ansell products complies in all material respects with FDA and FTC requirements.

2

PART III

Signature

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this amendment to the annual report on its behalf.

Ansell Limited

Registrant

/s/ Rustom Jilla

Rustom Jilla

Chief Financial Officer

Dated: January 14, 2004

PART III

Item 19 : Exhibits

Exhibit Index

7.1*	Computation of the Ratio of Earnings to Fixed Charges.
12.1	Certification of Chief Executive Officer or Equivalent Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
12.2	Certification of Chief Financial Officer or Equivalent Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
13.1*	Certification of Chief Executive Officer or Equivalent Pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code.
13.2*	Certification of Chief Financial Officer or Equivalent Pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code.

* Previously filed.