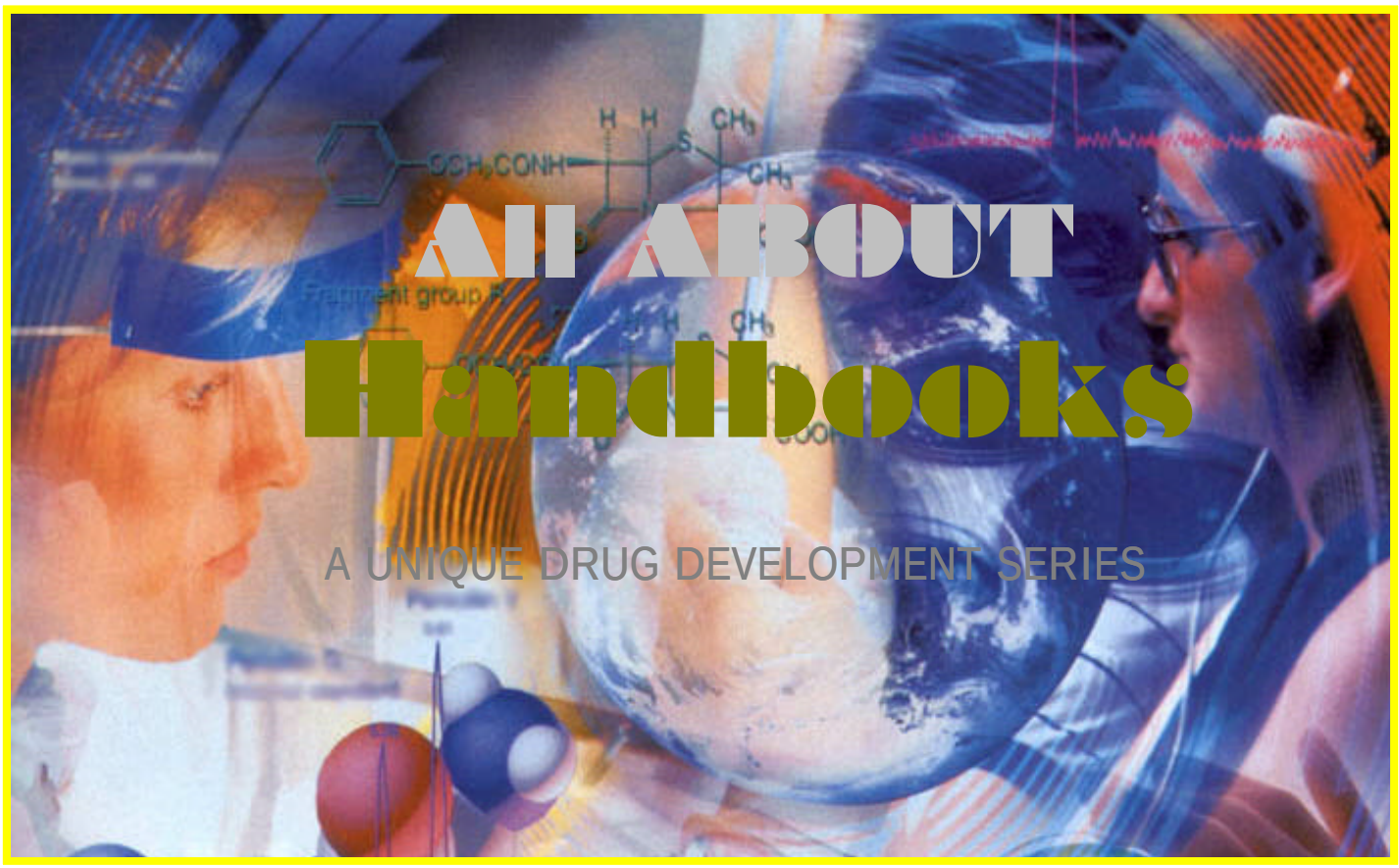
DRUG DEVELOPMENT

Hand 20 00 Books

Drug **D**evelopment & **M**anufacture for **P**harmaceutical **T**echnology **P**rofessions



FOR THE

DEVELOPMENTAL KNOW HOW
OF THE WORLDS TOP

GENERIC DRUGS

ISSN 0793 7601 - ISSN 0793 761X
Series Publication in association with:-

The International Association of Generic Drug Manufacturers

Handbook of Pharmaceutical Generic Development

Oral IR Tablets

Part ONE
DRUG DEVELOPMENT KNOW-HOW
&
Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW Edition
Year 2000

Handbook Volume in Part I & II
Drug Development

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Handbook of Pharmaceutical Generic Development a comprehensive and authoritative practical hands-on state-of-the-art handbook covering Generic know-how essential for developing the **21** ANDA Sections of an Immediate Release **Oral Tablet.**

Part One covers Pharmaceutical Drug Development and **Part Two** (ANDA Development) providing know-how for Development, Excipient and specification choice, Formulation, Dissolution, Stability, Scale-up, Process Qualification (Hardness Dissolution & U of C); Pivotal and final **validation** batches; Analytical, Cleaning and Process Validation; Incorporates essential development checklists, flowcharts, tabulations and key SOPs and critical documentation and OGD regulatory know-how for a successful review for a FDA approval, saving queue-time and money.

Essential development and submission know-how on **I**mmediate **R**elease **Oral Tablets** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with high-tech detailed ANDA Development (new formula & guidelines) for rapid flawless approval of ANDA submissions (Print or CD ROM).

Some Additional Titles:-
Bupropion, Buspirone, Diclofenac, Famotidine, Felodipine, Nabumetone, Naproxin, Piroxicam, Tamoxifen US/EU, Ticlopidine, Trazodone etc.

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ORAL DOSAGE FORMS

Table of Content - Summary

PART I - PHARMACEUTICAL DEVELOPMENT

Typical - Oral Tablet or Capsule

Handbook of
Pharmaceutical Generic Development

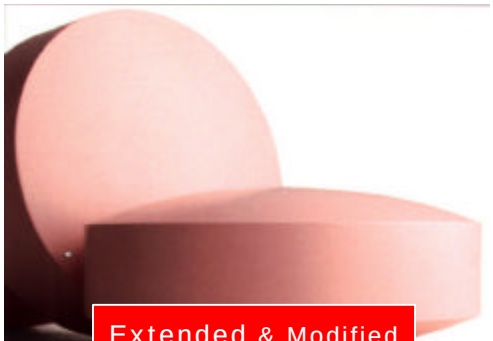
Controlled Release

Extended Solid Oral Dosage Forms

Tablets

Part ONE
Complete Drug Development Know-how
&
Part TWO
ANDA Formula & Development Technology

READY-TO-**GO**™ *SERIES*
Felodipine ER, Glipizide ER,
Sinemet ER, Naproxen DR,
Carbamazepine ER, Pentoxiphyllin ER



Extended & Modified
Release Dosage Forms

This Handbook of Pharmaceutical Generic Development is a fully comprehensive practical hands-on workbook covering modern drug development and the full **21** ANDA section interactions of a **Extended** or **Modified** **C**ontrolled **R**elease Oral Tablets or Caplets.

Part One (drug development) and **Part Two** (ANDA Development Know-how) provide Development, Master Drug Formulations, Key Processes, **Scale-up;** Process Optimization & Qualification; Stability; Pivotal and final Process Validation Know-how and Protocols; PAI, Analytical, Cleaning and Process **Validation** Do's & Don'ts. A reference for critical documentation and OGD regulatory know-how that is essential for a successful first time FDA review and approval, saving months of queue-time and market place sales.

Each and every regulatory guideline is covered in clear detail providing a development protocol for a totally omission-free file submission.

Over five years in preparation and claimed as the world's most authoritative and definitive work available on oral dosage form drug development from a generic industry viewpoint.

An Essential Reference for Development Pharmacists, R&D Chemists, QA/QC and Regulatory personnel. Allows management to understand the nuts and bolts on Generic ANDA DEVELOPMENT and filing and how to get to the market place - quickly and *on time*.

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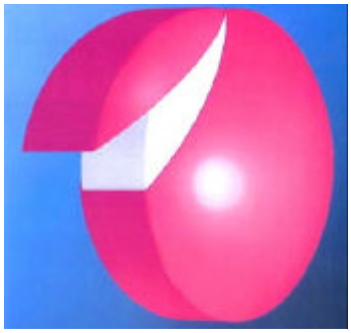

The International Association of Generic Drug Manufacturers

Handbook of Pharmaceutical Generic Development

Oral DR Tablets

Part ONE
DRUG DEVELOPMENT KNOW-HOW
&
Part TWO
ANDA DEVELOPMENT & FORMULATIONS

NEW 2000 Edition

This Handbook of Pharmaceutical Generic Development is a practical hands-on workbook covering state-of-the-art development for the full **22** ANDA development sections required for a **Oral DR Tablet** (Spay Granulation Enteric Coated Delayed Release). About 450 pages.

Part One covers pharmaceutical drug development and **Part Two** (ANDA Development) provide technical know-how for the Development, Formulation, Dissolution, Stability, Scale-up, Process Qualification; pivotal and final **validation** batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful first time FDA review and approval, saving months of queue-time and market place sales.

Essential development and submission know-how on Delayed Release **Oral Tablets** for advanced professional developers to understand the nuts-and-bolts on Delayed Release DEVELOPMENT side-by-side with detailed and practical ANDA development technology for rapid approval of ANDA files (Print or CD ROM).

ANDA DEVELOPMENT

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Title:- Handbook of Generic Drug Development
Delayed Release Tablets ISSN 0793-7601 / 0793-761X.

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The Development Handbook
NABUMETONE

SPECIAL FEATURES

Part One - Coverage from pre-formulation decisions to process validation of Generic ANDA - everything a researcher needs to know and more - detailing all essential development, formulation, scale-up manufacturing steps to current OGD 2000 regulations - for a fault-free file.

Developmental Checklists on the key Generic issues that the FDA routinely address during ANDA file and PAI review.

Checklists dovetail with a model Standard Operating Procedure for real-life, examples from **A** (actives) to **V** (validation).

Part Two

Authoritative model of an ANDA clarifying each document required to construct a successful ANDA (with side-by-side explanation notes and summaries) **A**llows management to understand the specific nuts and bolts on specific Generic ANDA development and filing, highlighting where the product's development dollars actually go.

The authoritative edition (1999) **Handbook** *Series* devoted to Generic Drug Development from pre-formulation to commercial batch production and final regulatory submission. Industry written in *two* easy-to-use complementary handbooks, with a unique modular format and *as-you-submit* data layout.

Part One describes key drug development steps. Each topic is a development stage and is supplemented with unique flowcharts, checklists, tablets, formula and selected key development SOPs.

Part Two covers the full ANDA development steps with substantial explanation notes and dovetails side-by-side with part one.

HANDBOOK OF PHARMACEUTICAL
GENERIC DEVELOPMENT
ORAL TABLET SERIES

Volumes consists of Part One & Two
Who this book is for:

***T**his Handbook of Pharmaceutical Generic Development* is an essential workbook for the full CMC and RA sections of the ANDA. Part One (development) and Part Two (ANDA Development) provide comprehensive Product Development; Formulation (high shear granulation), Process Optimization with key stability enhancing ingredients.

Highlights Process Qualification, Pivotal manufacture, CMS Documentation and Regulatory know-how that is essential for a successful review for a FDA approval, saving queue-time and money.

Essential reading for R&D / Development Pharmacists, Group & Project leaders, R&D Chemists, QA and Regulatory personnel.

The 24 volume development series maintains the Generic Handbook *Series* as current and authoritative.

ISSN Series No 0793-7407

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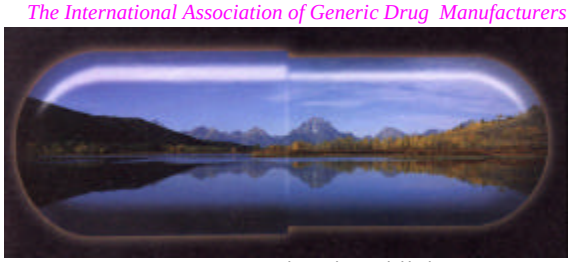

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ISSN 0793 8659 - ISSN 0793 8667

Handbook of Pharmaceutical Generic Development

Oral IR Capsules

NEW 2000 Edition

SINGLE ORAL DOSAGE FORM

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development
[with master formula & commercial processes]

***The** Handbook of Pharmaceutical Generic Development* is an essential workbook covering the full development, CMC and RA sections for a single dose **IR Capsule ANDA** development project.

Part One (Drug Development ±500 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art formula ±450 pages) provides essential **IR** capsule technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; detailing crucial documentation and OGD regulatory know-how that is essential for a successful review for FDA approval, saving queue-time and money. Full Review of every CMC/Bio FDA guideline issued.

Essential developmental know-how on **Oral IR Capsules** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with ***high-tech*** practical ANDA development know-how to produce utterly flawless files. (Print & CD ROM). Technological Level - Advanced.

ADDITIONAL TITLES - in PART II
Amoxicillin 250 / 500mg;Azithromycin 250/600mg Cefaclor 250/500mg
Clomipramine 25/50/75mg
Etodolac 200/300 mg; Fluoxetine 10/20mg
Gabapentin 100/200/300mg
Piroxicam 10/20mg; Tolmetin 600 mg.

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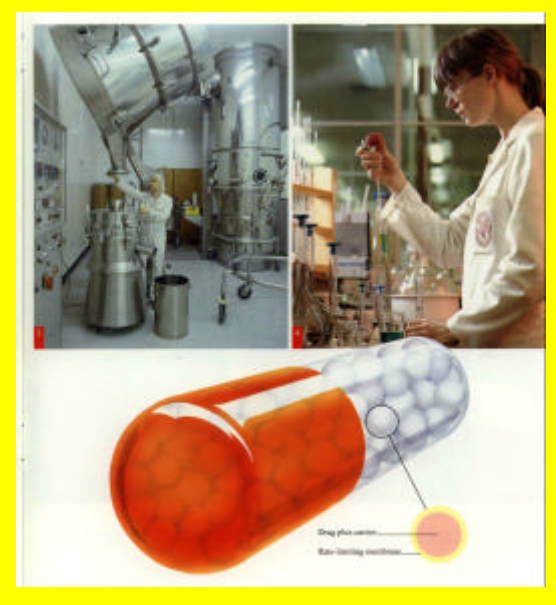
NEW Advanced Edition - Jan 2000

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development



Each Volume Includes:
Development Handbook
ANDA Development
[with master formula & commercial processes]

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Formula & Manufacturing Details for Coated Sugar Spherical (bead) Technology Coated Pellets and Coating Highly Soluble Crystals (SR KCL 1200 mg, 20-40 mesh)

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Handbook of Pharmaceutical Generic Development

Oral ER CAPSULES

The Handbook of Pharmaceutical Generic Development is an essential workbook covering the Full Development, CMC and QA/RA sections for a **ER & SR [MR] CAPSULE** development program.

Part One (**ER** Development ±450 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art **MR** formulae and manufacturing processes ±350 pages) provides essential ER Capsule Technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and Large Scale Validation batches using both pan and Wurster Spray Granulators (GPCG 60/120); ER analytical methodology; Dissolution, cleaning and process validation; essential documentation and OGD Regulatory / R&D know-how, essential for a successful review & FDA approval, saving queue-time and money.

Essential development know-how on **Oral ER/SR Capsule** for advanced developers to understand the nuts-and-bolts on Generic MODIFIED RELEASE DEVELOPMENT with a ***high-tech*** detailed ANDA development to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.

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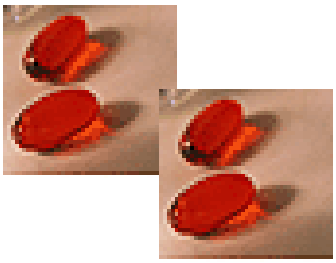

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Handbook of Pharmaceutical Generic Development

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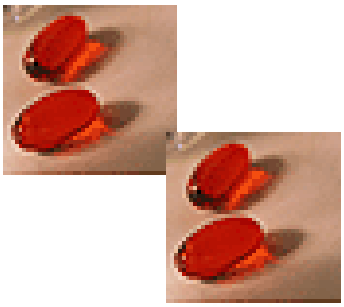
Soft Gelatin Capsules

Part ONE
DRUG DEVELOPMENT
&
Part TWO
Regulatory ANDA Development
[with master formula & commercial processes]



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***T**he Handbook of Pharmaceutical Generic Development* is an essential workbook covering the full development, CMC and RA sections for a single dose **SG Capsule ANDA** development project.

Part One (Drug Development ±500 pages) and **Part Two** (ANDA Development with detailed commercial and state-of-the-art formula ±450 pages) provides essential **SG** capsule technology know-how on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; detailing crucial documentation and OGD regulatory know-how that is essential for a successful review for FDA approval, saving queue-time and money. Full Review of every CMC/Bio FDA guideline issued.

Essential developmental know-how on **Oral SG Capsules** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with ***high-tech*** practical ANDA development know-how to produce utterly flawless files. (Print & CD ROM). Technological Level - Advanced.

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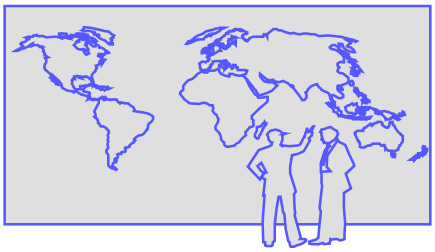

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Handbook of Pharmaceutical Generic Development

Oral LIQUIDS

LIQUID DOSAGE FORMS

NEW Edition
March 2000

This Handbook of Pharmaceutical Generic Development is a practical hand-on workbook covering essential liquid formulations such as syrup and sugar-free Paracetamol; Dexchlorpheniramine + Pseudoephedrine; Codine Phosphate + Ephedrine HCl; Pheniramine Maleate; Bromhexine; Oxolamine; Terbutaline; Sodium Valproate formulations.

Part One provide general and specific Product Development, Pre-formulation, Final Formulation, Scale-up Process Qualification; pivotal and final validation batches; analytical, cleaning and process validation; Essential documentation and regulatory know-how that is essential for a successful review for a EU/FDA approval, saving queue-time and money.

Part Two (ANDA Development) highlights the **21** ANDA sections of **Oral Liquids** (both normal & reconstituted dosage forms).

Essential development and submission know-how on **Oral Liquids** for professional developers to understand the nuts-and-bolts on Generic ANDA DEVELOPMENT with a high-tech detailed working model ANDA.

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Part TWO
ANDA Development Technology

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NEW Edition
Jan 2000

Handbook of Pharmaceutical Generic Development

ISBN 965 492 004-2

Part ONE
DRUG Development Know-how
&
Part TWO
ANDA Development Technology

Drug Development

ANDA Development

Cephalosporins
Synthetic Penicillins
Azithromycin
SMX-TMP
(Cotrimoxazole)

Oral Suspensions

The Handbook of Pharmaceutical Generic Development is an essential workbook covering the full CMC & Bio and RA sections of normal **Oral Suspension** ANDA / AADA and a **Suspension for Reconstitution.**

Part One (Development ISBN 965 492 004-2) and **Part Two** (ANDA Development - ISBN 965492005-0 with detailed commercial and state-of-the-art formula) provides essential know-how technology on all aspects of; Development, Formulation, Scale-up, Process Optimization & Qualification; Pivotal and large scale Validation batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful review for a FDA approval, saving queue-time and money.

Essential development know-how on **Oral Suspensions and Suspensions for Reconstitution** professional developers to understand the nuts-and-bolts on Generic MODIFIED RELEASE DEVELOPMENT with a ***high-tech*** detailed ANDA development to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.

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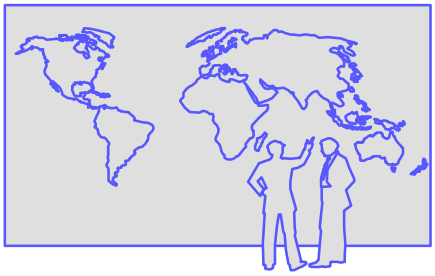

Handbook of Pharmaceutical Generic Development

ISSN 0793 7601 - ISSN 0793 761X

Inhalation Aerosols

Handbook Volume Consists of:
Complete Drug Development
Complete ANDA Development

Part ONE
DRUG Development Know-how
&
Part TWO
ANDA Development Technology

The *Handbook of Pharmaceutical Generic Development* is a practical hand-on workbook covering the full **22** ANDA sections of ORAL & NASAL **Inhalation Aerosol (MDI** Aerosol solutions and suspensions).

Part One (Full Development ISBN 0793 7601) **and Part Two** (Detailed ANDA Development covering all 22 Sections - ISSN 0793-761X) provide Development, Formulation, Scale-up Process Qualification; pivotal and final validation batches; analytical, cleaning and process validation; essential documentation and OGD regulatory know-how that is essential for a successful review for a FDA approval, saving queue-time and money.

Essential development know-how on **Oral & Nasal Inhalation Aerosols for** professional developers to understand the nuts-and-bolts on Generic Dosage Form DEVELOPMENT with ***high-tech*** detailed ANDA development know-how to produce flawless files. (Print & CD ROM). Presented at an Advanced Technological Level.)

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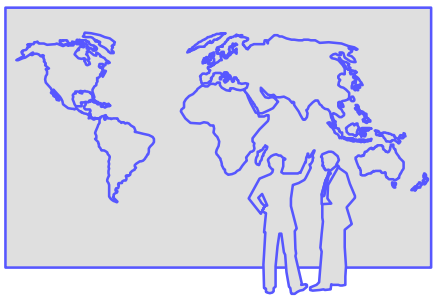

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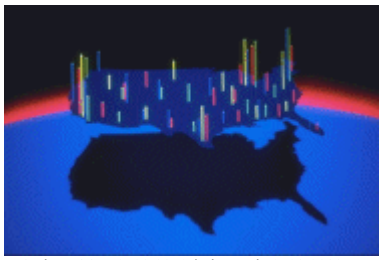

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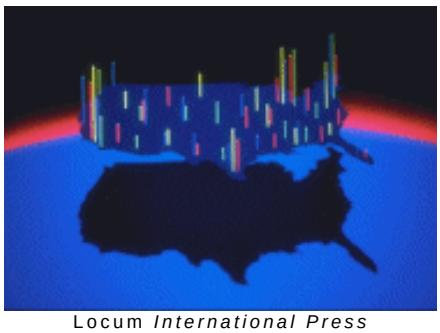

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