

# NEWPORT PREMIUM

## 快速指南系列：增强版

### 希望与您一起在工作中充分利用 NEWPORT 更新功能

本快速指南包含 2015 年 9 月发布的 Newport PREMIUM 数据库中新增内容和功能。新增内容如**全球批准信息**、**标签信息**和**监管数据**可在产品或公司记录中查询。新版界面经过了重新设计，并改进功能模块，重排内容以便更直观地访问。

1. **新增批准**页面 (Approvals)，在原版产品信息 (Product Information) 基础上将所有批准数据合并至一个表格。

| Product Profile     | Approvals  | Launches           | US Market Stats        | R & D    | Patents       | US Patent Challenges | API                | Pathways | Deals | Market CI | Regulations | Product Changes |
|---------------------|------------|--------------------|------------------------|----------|---------------|----------------------|--------------------|----------|-------|-----------|-------------|-----------------|
| sildenafil citrate  |            |                    |                        |          |               |                      |                    |          |       |           |             |                 |
| Worldwide Approvals |            |                    |                        |          |               |                      |                    |          |       |           |             |                 |
| Excel Export        |            |                    |                        |          |               |                      |                    |          |       |           |             |                 |
| Country             | Trade Name | Active Substance   | Holder                 | Status   | Approval Date | Agency               | Application Number |          |       |           |             |                 |
| EU                  | Vizarsin   | sildenafil citrate | Krka, d.d., Novo mesto | Approved | 21 Sep 2009   | EMA                  | EMA/H/C/001076     |          |       |           |             |                 |
| EU                  | Patrex     | sildenafil citrate | Pfizer Limited         | Approved | 15 Sep 1998   | EMA                  | EMA/H/C/000204     |          |       |           |             |                 |

图 A: **新增全球批准数据** (Worldwide Approvals) 引入了欧洲集权程序 (CP) 批准信息。同类条目在公司记录中也可查询获得。进一步国家级别的批准数据将在未来更新中考虑加入。

2. 在产品和公司记录中，**美国申报 & 批准** (US Filings/Approvals) 表格中**新增申报 & 批准类型** (US Filing/Approval Type) 选项，目前可选 505b2、OTC 以及其他批准类型等。

| US Filings & Approvals  |           |                   |          |           |                         |                         | Excel | Export |
|-------------------------|-----------|-------------------|----------|-----------|-------------------------|-------------------------|-------|--------|
| Pages: 1 2 3 4 5        |           |                   |          |           |                         |                         |       |        |
| Trade Name              | Applicant | Active Ingredient | Strength | Dose Form | Route of Administration | Filing/Approval Details |       |        |
| Abacavir Sulfate 20mg   | Cipla Ltd | abacavir sulfate  |          | Solution  | Oral                    | Filing/Approval Type    |       |        |
| Abacavir Sulfate 300 MG | Cipla Ltd | abacavir sulfate  |          | Tablet    | Oral                    | ANDA                    |       |        |
| Abacavir Sulfate, 60mg  | Cipla Ltd | abacavir sulfate  |          | Tablet    | Oral                    | ANDA                    |       |        |
|                         |           |                   |          |           |                         | 505(b)(2)               |       |        |

图 B: 在产品和公司记录中，**美国申报 & 批准** (US Filings/Approvals) 表格中**申报 & 批准类型** (Filing/ Approval Type) 可选择查询。

3. **新增上市**页面 (Launches)，以原版制剂信息 (Dose Form Detail) 为基础，合并 IMS 上市数据，**新增标签信息**表格 (Label Information)，其中信息来源于美国生产商标签信息，包括批准持有人，实际 FDF 生产者，重新包装者，重新贴标签者以及负责分析者 (批放行) 以及 API 来源公司等信息。

| Product Profile          | Approvals           | Launches | US Market Stats   | R & D                           | Patents                    | US Patent Challenges    | API                            | Pathways      | Deals | Market CI | Regulations | Product Changes |
|--------------------------|---------------------|----------|---|---------------------------------|----------------------------|-------------------------|--------------------------------|---------------|-------|-----------|-------------|-----------------|
| sildenafil citrate       |                     |          |   |                                 |                            |                         |                                |               |       |           |             |                 |
| Label Information        |                     |          |   |                                 |                            |                         |                                |               |       |           |             |                 |
| Pages: 1 2               |                     |          |   |                                 |                            |                         |                                |               |       |           |             |                 |
| Excel Export Filter Data |                     |          |   |                                 |                            |                         |                                |               |       |           |             |                 |
| Trade Name               | Dose Form           | Strength | Labeler   | Manufacturer                    | Repackager                 | Analysis                | API Source                     | Label Details |       |           |             |                 |
| Sildenafil               | TABLET, FILM COATED | 20 mg    | Apotex Corp.  | Apotex Research Private Limited |                            |                         |                                | Revision Date |       |           |             |                 |
| Sildenafil               | TABLET, FILM COATED | 20 mg    | Apotex Corp.  | Apotex Research Private Limited |                            |                         |                                | 02 Apr 2015   |       |           |             |                 |
| Viagra                   | TABLET, FILM COATED | 100 mg   | Lake Erie Medical Surgical and Supply DBA Quality Care Products LLC | Pfizer PGM                      | Pfizer Pharmaceuticals LLC | Pfizer Laboratories Div | Pfizer Ireland Pharmaceuticals | 28 Dec 2011   |       |           |             |                 |

图 C: 上市页面 (Launches) 中包含**标签信息** (Label Information)。同类条目在公司记录中也可查询获得。进一步国家级别的批准数据将在未来更新中考虑加入。

4. 另外，在产品和公司记录已上市药品剂型信息表中，**新增上市区域** (Launch regions) 选项，以便快速筛选过滤。

Product Profile Approvals Launches US Market Stats R & D Patents US Patent Challenges API Pathways Deals Market CI Regulations Product Changes Set Alert

**sildenafil citrate**  
Show Product Family ask ims

Launched Drug Forms Detail  
Pages: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87

| Dose Form | Strength | Active Ingredient  | Trade Name        | Marketer    | Group Info   | Launch Country  |
|-----------|----------|--------------------|-------------------|-------------|--|-----------------|
|           |          |                    |                   |             | Name   |                 |
| Capsule   | 100MG    | sildenafil citrate | ERECTRA           | PROCAPS     | Procaps SA   | Ukraine         |
| Capsule   | 100MG    | sildenafil citrate | HELPIIN LIQUICAPS | RECALCINE M | Abbott Laboratories                                  | Chile           |
| Capsule   | 100MG    | sildenafil citrate | SILDENAFIL-GENFAR | GENFAR      | Sanofi   | Central America |
| Capsule   | 25MG     | sildenafil citrate | ALTUS             | UNIMED      | Solvay SA  | Peru            |
| Capsule   | 25MG     | sildenafil citrate | ERECTRA           | PROCAPS     | Procaps SA   | Ukraine         |
| Capsule   | 25MG     | sildenafil citrate | GELPIN            | COLMED      | Colombiana de Suministros Medicos Hospitalarios Ltda | Colombia        |
| Capsule   | 25MG     | sildenafil citrate | HELPIIN LIQUICAPS | RECALCINE M | Abbott Laboratories                                  | Chile           |

Filter this table...  
Dose Form  
Capsule, Extended Release  
Gel  
Launch Regions  
Asia Pacific  
Eastern Europe  
Latin America  
Filter Clear Close

图 D: 上市页面 (Launches) 新增上市区域 (Launch regions) 选项，目前包括亚太、东欧、拉美、中东和非洲、北美和西欧等区域。同类选项也可在公司记录上市 (Launches) 表格中获得。

5. 新增全球包装价格主题检索 (Worldwide Pack Price Focused Search)，可以按照产品名称、剂型、给药途径、EPHRA 目录、经销商名称、企业（集团）名称、上市国家和上市日期等，对包装价格进行检索。

Product / Company Target Products Search Target Companies Search Focused Search

Worldwide Pack Prices Focused Search search type: Worldwide Pack Prices

Product Name ends with sodium Search by Trade Name

Dose Form Capsule

Route of Administration Oral

Therapeutic Category (EPHRA) C - Cardiovascular system

Marketer Company Name contains pharma

Corporate Group Name begins with

Launch Country In Eastern Europe or Latin America Not in

Pack Launch Date is after 1/1/2015

Search Criteria  
Product Name ends with sodium and  
Dose Form Capsule and  
Route of Administration Oral and  
Therapeutic Category (EPHRA) C - Cardiovascular system and  
Marketer Name contains pharma and  
Launch Country In Eastern Europe or Latin America and  
Pack Launch Date is after 1/1/2015  
Search Reset

图 E: 全球包装价格 (Worldwide Pack Price) 现可在主题检索中获得。

5a. 通过目标产品检索 (Target Product Search)、目标制剂公司检索 (Target Dose Company Search) 和全球上市主题检索 (Worldwide Launches Focused Search) 入口，上市国家 (Launch Country) 检索除了可选择以往一个或者多个国家以外，新增一个或多个预设的地理区域可供选择。

Product / Company Target Products Search Target Companies Search Focused Search

TARGET PRODUCT SEARCH

Sales Trend growth less than % Select a region

Launched Products In Not in  
Asia Pacific  
Eastern Europe  
Latin America  
Middle East & Africa  
North America  
Western Europe  
Algeria  
Argentina  
Australia  
Austria  
Bangladesh  
OK

First Marketing Authorization in Europe\* is after MM/DD/YYYY Country

Pack Launch Date is after MM/DD/YYYY

Marketer Corporate Group begins with

图 F: 全球包装价格 (Worldwide Pack Prices) 可在主题检索中获得。上市国家 (Launch Country) 目前包括亚太、东欧、拉美、中东和非洲、北美和西欧等区域，此选项可在目标产品检索 (Target Product Search)、目标制剂公司检索 (Target Dose Company Search) 和全球上市主题检索 (Worldwide Launches Focused Search) 入口获得。

6. 美国申报 & 批准主题检索 (US Filings & Approvals Focused Search) 中**新增批准类型** (Approval Type) 选项，提供 505b2, 510k, ANDA, BLA, HDE, NDA 和 PMA 等细分类型选择。

图 G: 美国申报 & 批准主题检索 (US Filings & Approvals Focused Search) 中**新增批准类型** (Approval Type) 选项。

7. **新增研发 (R&D)** 页面，合并了原版产品概述 (Product Profile) 和剂型信息 (Dose Form Detail) 表格中所有 Ph III 期药物模块 (Ph III Drug Module) 的信息和内容。*注：产品和公司记录中 Ph III 期药物模块 (Ph III Drug Module) 内容需要额外订阅才能查看。*
8. 美国市场份额模块 (US Market Share Module) 中**新的“早期回顾”** 数据将数据延迟减少至 3-6 个月，保持每季度更新一次。*注：美国市场份额模块 (US Market Share Module) 需要额外订阅才能查看。*
9. 公司报告表格中，**企业集团信息** (Corporate Group Profile) **新增** 一键订阅可得的科睿唯安财务与风险 (Clarivate Finance & Risk) 加强版**尽职调查报告** 和美国 **FDA GDUFA** 状态信息。

| Corporate Group Detail   |  | Deals                            | Subsidiaries | R & D | Approvals | Launches               | Patents | API | Regulations | Corporate Group Changes | Set Alert |
|--|--|----------------------------------|--------------|-------|-----------|------------------------|---------|-----|-------------|-------------------------|-----------|
| <b>Cipla Ltd</b>   |  |                                  |              |       |           |                        |         |     |             |                         |           |
| Cipla Ltd<br>289 Belasis Road, Mumbai Central.<br>Mumbai, Maharashtra 400 008 India<br>phone: 91 22 23082891<br>fax: 91 22 23070013<br>web: <a href="http://www.cipla.com">www.cipla.com</a> |  | Corporate Group Type:            |              |       |           | API/Biotech/US Generic |         |     |             |                         |           |
|  |  | US FDA Warning Letters:          |              |       |           |                        |         |     |             |                         |           |
|  |  | Hold US ANDAs:                   |              |       |           | Yes                    |         |     |             |                         |           |
|  |  | Latest GDUFA facility fees paid: |              |       |           | Yes                    |         |     |             |                         |           |
|  |  | Registered facilities as of:     |              |       |           | 06 May 2015            |         |     |             |                         |           |

图 H: 企业集团信息 (Corporate Group Profile) 中**新增美国 FDA GDUFA** 状态信息和**请求尽职调查报告**按钮。

10. **新增药政法规** 页面 (Regulations page) 将直接链接至 Cortellis™ Regulatory Intelligence 数据库，提供全球药政法规对比，以及所有国家级别的仿制药法规要求。*注：Cortellis™ Regulatory Intelligence 需要额外订阅才能查看。*

| Global Regulatory Comparison Topics |                           |                                 |                                |  |  |   |
|-------------------------------------|---------------------------|---------------------------------|--------------------------------|--|--|---|
| Global Comparison Tables            | <a href="#">Generics</a>  | <a href="#">Biosimilars</a>     | <a href="#">Stability Data</a> | <a href="#">Product Certificates (CPP)</a> | <a href="#">Approval Times</a>           | <a href="#">Quality Systems &amp; GXP</a> |
| For Non-Subscribers                 | <a href="#">User Fees</a> | <a href="#">eCTD Acceptance</a> | <a href="#">Pharmacopoeias</a> | <a href="#">Manufacturing Changes</a>      | <a href="#">Packaging &amp; Labeling</a> | <a href="#">Transparency</a>              |

  

| Local Regulatory Requirements |                                      |                             |                              |                            |                          |                         |
|-------------------------------|--------------------------------------|-----------------------------|------------------------------|----------------------------|--------------------------|-------------------------|
| Country Regulations           | How To Market Generics & Biosimilars | Drug Master File Procedures | GMP Compliance & Inspections | Import & Export Procedures | Drug Application Formats | Pricing & Reimbursement |
| For Non-Subscribers           | <a href="#">Sample</a>               | <a href="#">Sample</a>      | <a href="#">Sample</a>       | <a href="#">Sample</a>     | <a href="#">Sample</a>   | <a href="#">Sample</a>  |
| Algeria                       | Coming Soon                          | Coming Soon                 | Coming Soon                  | Coming Soon                | Coming Soon              | Coming Soon             |
| Argentina                     | Available                            | Available                   | Available                    | Available                  | Available                | Available               |
| Australia                     | Available                            | Available                   | Available                    | Available                  | Available                | Available               |

图 I: **注册申报** (Regulatory Filings)

11. API 页面 (API page) 原版进口数据表格中的内容与 DMF 和 COS 内容合并为一张**新表**。

| Active Ingredient  | Filing | Holder                          | Manufacturer                    | Date        | Number   | Status | Type      | Description  |
|--------------------|--------|---------------------------------|---------------------------------|-------------|----------|--------|-----------|--|
| sildenafil         | US DMF | Mylan Laboratories Inc          | Mylan Laboratories Limited      | 26 Dec 2012 | D026777  | Active | II        | SILDENAFIL   |
| sildenafil         | US DMF | Polpharma                       | Polpharma                       | 19 May 2014 | D028319  | Active | II        | SILDENAFIL BASE                                      |
| sildenafil citrate | US DMF | Nuray Chemicals Private Limited | Nuray Chemicals Private Limited | 21 Aug 2009 | D023067  | Active | II        | SILDENAFIL CITRATE (NON-STERILE BULK DRUG SUBSTANCE) |
| sildenafil citrate | COS    | Maprimed SA                     | Maprimed SA                     | 23 Feb 2015 | 2013-100 | Valid  | Chemistry |  |

图 J: **注册申报** (Regulatory Filings) 表格可在 **API** 页面中查询。

12. 产品和公司记录中，API 生产状态表格中 DMF 信息列**新增可引用的 US DMF** (Available for Ref US DMF) 代替原版中的“已完成” (Completed)。

DMF Info

Active US DMF

Active US DMF

Japanese DMF

Korean DMF

Available for Ref US DMF

13. API 生产状态表格 (API Manufacturing Status) 中 API 生产商 (API Manufacturer) 可选项**新增美国 GDUFA 付费日期** (US GDUFA Fee Payment Date) 和**生产厂注册日期** (Facility Registration Date)。

API Manufacturer Info

Country

Country

City

GDUFA Fee Payment Date

Facility Reg. Date

FDA Warning Letter Date

FDA Insp Date

14. 子公司 (Subsidiary Company) 记录中**新增生产场地信息**，包括美国 FDA GDUFA 生产场地付费和自我认定注册记录的完成情况。

| Company Detail   | Approvals | Launches | Patents | API | Capabilities | Regulations |   |
|--|-----------|----------|---------|-----|--------------|-------------|---|
| <b>Dr Reddy's Laboratories Ltd</b>   |           |          |         |     |              |             | Corporate Group: <a href="#">Dr Reddy's Group</a> |
| <b>Dr Reddy's Laboratories Ltd</b><br>Unit V, Peddadevulapally Village<br>Tripuraram<br>Nalgonda, Telangana 508 207<br>India |           |          |         |     |              |             |   |
| Phone:   |           |          |         |     |              |             |   |
| Fax:   |           |          |         |     |              |             |   |
| Website:   |           |          |         |     |              |             | <a href="#">www.drreddys.com</a>                  |
| US FDA Warning Letters:  |           |          |         |     |              |             |   |
| Latest GDUFA facility fees paid:   |           |          |         |     |              |             | Yes   |
| Registered facility as of:   |           |          |         |     |              |             | 16 Mar 2015                                       |

图 K: 公司详情中的**新增生产场地信息**

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