

NEWPORT INDUSTRY INFORMATION

GLOSSARY OF INDUSTRY TERMS



ABBREVIATED NEW DRUG APPLICATION (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic [drug product](#) in the US.

Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is [bioequivalent](#).

Once approved, an applicant may manufacture and market the generic drug product.

ACTIVE MOIETY

In chemistry, a moiety is a group of atoms forming part of a molecule. In the case of a pharmaceutical product, the active moiety is that part of the molecule of an active substance which gives it its therapeutic effect.

ACTIVE PHARMACEUTICAL INGREDIENT

An active pharmaceutical ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Most generic companies depend on independent API manufacturers for the active ingredients that go into their products. APIs are important because their successful development and manufacture is critical to generic development and production.

From a generic company perspective, knowledge of API availability and bulk producers' manufacturing capabilities and regulatory histories facilitates business development and partnering decisions. From a brand company perspective, knowledge of activity in the API market can be predictive of generic activity well in advanced of brand exclusivity expiry.

Alternative terms for API include "bulk", "raw material", and "pharmaceutical ingredients".

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

A patent resource pooling agreement that covers Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

ANDEAN COMMUNITY OF NATIONS

A trade bloc comprising Bolivia, Colombia, Ecuador and Peru. Venezuela withdrew membership in 2006.

APPROVAL LETTER

An official communication from FDA to a [new drug application \(NDA\)](#) sponsor that allows the commercial marketing of the product.

ATC CODE

Anatomical Therapeutic Chemical classification system.

BIOAVAILABILITY

The rate and extent at which an [active pharmaceutical ingredient](#) is absorbed (both speed and amount) by the body when introduced in a given dosage form (capsule, tablet, injectable, suppository, etc).

BIOEQUIVALENCE

Two medicines are bioequivalent when they contain the same amount of an identical [active pharmaceutical ingredient](#), and when their [bioavailability](#) is the same when administered in equal doses under equal conditions. Strict scientific criteria exist for running bioequivalence studies.

BIOGENERIC/BIOSIMILAR PRODUCT

An off-patent [biological medicinal product](#) which is produced by manufacturers other than the originator and which is similar to the originator product. Biogenerics are sometimes called biosimilar or follow-on biologic products because [biological products](#) produced by different manufacturers are not strictly identical, but similar.

Once approved by the competent authorities, biosimilar/biogenic products are not significantly different in terms of quality, safety and efficacy from the originator product.

NEWPORT PRODUCT OFFERINGS

[For Generics & API Manufacturers](#)

[Newport Horizon Premium™](#)

[Newport Horizon Global™](#)

[Newport Horizon Sourcing™](#)

[For Innovators](#)

[Newport Vision Premium™](#)

[Newport Vision CI™](#)

[Newport Vision Sourcing™](#)

INDUSTRY LINKS

[Governmental / Regulatory](#)

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THOMSON REUTERS

BIOLOGIC LICENSE APPLICATION (BLA)

Biological products are approved for marketing in the US under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product.

A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical affects of the [biologic product](#). If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.

BIOLOGIC PRODUCT

A biologic product is any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries. Biologic products are a subset of [drug products](#) distinguished by their manufacturing processes (biological process vs. chemical process). In general, the term "[drugs](#)" includes biologic products.

BIOLOGICAL MEDICINAL PRODUCT

A medicine where the active substance is a biological substance as opposed to a chemical substance. The biological substance is produced by or extracted from a biological source.

BOLAR AMENDMENT

Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), in which the Federal Circuit held that the manufacture, use, or sale of a patented invention during the term of the [patent](#) constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval.

BRAND NAME DRUG

A brand name drug is a [drug](#) marketed under a proprietary, trademark-protected name.

CAS NUMBERS

Chemical Abstracts Service Registry numbers. A unique, numerical designation for every chemical, including pharmaceuticals.

CAS numbers are used primarily by chemists to identify different [drugs](#), since the text names of drugs can vary. CAS numbers are assigned by the American Chemical Society's Chemical Abstracts Service (CAS), generally determined with the rules of the International Union of Pure and Applied Chemistry (IUPAC) and the International Union of Biochemistry (IUB). Registry numbers are assigned randomly and do not imply any compositional or other meaning.

CENTRALISED PROCEDURE

The Centralised Procedure is one of two different routes for authorizing medicinal products for marketing and use in the European Union. It entails submission of an application to the [EMA](#) and is obligatory for certain pharmaceuticals, such as those derived from biotechnology, and is optional for others.

The marketing authorization granted is valid in all countries of the EEA. See: [Decentralised Procedure](#) and [Mutual Recognition Procedure](#).

CERTIFICATES OF SUITABILITY (CEP)

From the perspective of the European Pharmacopoeia: where the Convention on the Elaboration of a European Pharmacopoeia is applied, it is essential to have a procedure that allows the manufacturer of a substance to provide proof that the purity of the substance is suitably controlled by the monograph of the European Pharmacopoeia.

The procedure described in Resolution AP-CSP (99) 4 of the Council of Europe satisfies this need through certificate of suitability monographs of the European Pharmacopoeia granted by the EDQM.

Further support for EU wide certificates is supplied by directives 75/318/EEC amended and 81/852/EEC amended on quality, safety and efficacy criteria for marketed medicinal products. The requirements on the quality of active substances are given in the Guideline "Requirements in relation to active substances" published in Vol III, add No 2, May 1992 (pp 29-34) of the European Community regulations on medicines.

The European Pharmacopoeia is comprised of 28 parties to the Convention: 26 member states of the Council of Europe (including the 15 states of the European Union): Austria, Belgium, Croatia, Cyprus, the Czech Republic, Denmark, Finland, the former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom; one state not a member of the Council of Europe: Bosnia and Herzegovina; and the Commission of the European Communities.

CTD

Common Technical Document.

DATA EXCLUSIVITY

In the EU, the period of time during which the medicines authorities are not allowed to consult the dossier of an originator pharmaceutical to verify the safety and efficacy of the [active moiety](#) in the application for marketing authorization of a generic medicine.

Data exclusivity periods may extend beyond the [patent](#) protection period of a pharmaceutical product, thus delaying the availability of lower-priced generic medicines to patients.



DECENTRALISED PROCEDURE

The Decentralized Procedure represents a new means of applying for marketing authorizing for a generic medicine in the EU. It consists of a single application submitted simultaneously to all Member States, who will determine the merits of the application collectively.

DOSAGE FORM

A dosage form is the physical form in which a [drug](#) is produced and dispensed, such as a tablet, a capsule, or an injectable.

DRUG

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- [Biologic products](#) are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process vs. biological process).

DRUG MASTER FILE (DMF)

A confidential document filed by API manufacturers and referenced in an Abbreviated New Drug Application (ANDA) or New Drug Application (NDA).

Since a DMF is required to supply bulk material to the US market, API manufacturers with a large number of DMFs tend to be more reliable in terms of quality, regulatory standing, and ability to meet cGMP. It should be noted, however, that DMFs are only reviewed after a dose form filing references that DMF. Therefore, not all DMFs are reviewed by the FDA, and the possession of a DMF for a product does not ensure that a manufacturer is producing that product or able to supply it to the US.

There are five types:

- Type I: Facilities DMF. Manufacturing site, facilities, operating procedures and personnel not specific to a drug substance. Type I DMFs are no longer accepted by the FDA but old ones remain on file.
- Type II: Drug substance DMF. Drug substances, intermediates and materials used in their preparation. A Type II DMF can also cover dosage form drugs manufactured under contract for another company which would file an ANDA. Type II is the most common form of DMF.
- Type III: Packaging material DMF. Packaging materials, from bottles and caps to PVC resin used

in their manufacture must be covered in a DMF or other FDA document (such as an NDA).

- Type IV: Excipient, colorant, flavor, essence or material DMF. Excipients are chemically inactive substances such as starches or cellulose used to bind drug powder together so that it can be pressed into a tablet. Other examples include flavorings in children's drugs, alcohol in liquids, etc.
- Type V: FDA accepted reference information not included in Types I-IV.

Starting in September, 1998 the FDA began to declare some DMFs inactive. The criteria for judging a DMF to be inactive, as listed on the FDA website, include:

- The holder requested that the DMF be retired or inactivated.
- DMFs filed more than 6 years ago which have had no activity.
- DMFs filed more than 6 years ago which have had only one or two submissions within the past 6 years.
- DMFs which have not had an annual update from the holder for the past 5 years.

Historically, filing a DMF was a way for less established firms to claim a degree of credibility when trying to sell into the US market and even in other regulated markets. However, since DMFs are only reviewed when an ANDA or NDA references them, a DMF that has not been referenced is of questionable value even if the DMF holder thinks having a DMF makes them look legitimate. Filing DMFs without any customers in the US has become much less common, so more recent DMFs are a better indicator of intent to manufacture than older DMFs.

DRUG PRODUCT

The finished [dosage form](#) that contains a [drug](#) substance, generally, but not necessarily in association with other active or inactive ingredients.

EDQM

European Directorate for the Quality of Medicines of the Council of Europe.

EMEA

The European Medicines Agency is responsible for evaluating medicinal products and providing advice on research and development programs and maintaining various databases available to healthcare professionals and the public. It is also responsible for granting single European marketing authorizations for medicines through the Centralized Procedure and for arbitrating in case of disputes.



EU

A trade bloc comprising: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

EURASIAN PATENT CONVENTION (EAPO)

A regional organization to grant Eurasian patents, comprising: the Republic of Armenia, the Azerbaijan Republic, the Republic of Belarus, the Republic of Kazakhstan, the Kirghiz Republic, the Republic of Moldova, Russia, the Republic of Tajikistan, Turkmenistan.

EUROPEAN PATENT ORGANISATION (EPO)

A patent granting body comprising: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom.

EXPIRY DATE

The end date of the [patent](#) term. The duration of a patent differs from country to country and the starting point of patent life may be the local filing date, publication date, date of grant, etc. As a general rule, the expiry date is usually not later than 21 years from [priority](#) (ie 20 years from local filing in most countries).

When a patent has reached the end of its term, it is said to have expired. Patents may cease before the normal expiry date for a variety of reasons e.g. for non-working of the invention, or through non-payment of renewal fees.

FDA

United States Food and Drug Administration.

FIRST MARKETING AUTHORIZATION

The First Marketing Authorization information is the date and country of the first marketing authorization within the EU. The date of the first EU marketing authorization is the reference date for all [SPCs](#) granted in the EU.

GATT

General Agreement on Trade and Tariffs, superseded by the [World Trade Organization \(WTO\)](#) in January 1995. The GATT 1994 Agreement is an integral part of the [World Trade Organization Agreement](#).

GENERIC DRUG

A generic drug is the same as a [brand name drug](#) in dosage, safety, strength, how it is taken, quality, performance, and intended use. In the case of the US, before approving a generic [drug product](#), the

FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations.

By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

GRANDFATHERING

A clause within the implementing language for [GATT](#) in the US that allows a company that had made "substantial investment" in a generic pharmaceutical prior to the GATT extension of certain patent [expiry dates](#) to market a generic version of the product on which the [patent](#) has been extended provided that the generic company pay a "reasonable remuneration" to the [patentee](#).

Neither "substantial investment" nor "reasonable remuneration" were defined in the GATT implementing legislation and the courts are expected to decide how to define these terms.

HATCH-WAXMAN ACT

See [Waxman-Hatch Act](#).

ICH

International Conference on Harmonization.

INN

International Non-proprietary Names. The official, international standard for generic pharmaceutical names. Similar to the [USAN](#), but there is some variation between the names. NPS uses the INN and provides appropriate synonyms from the USAN as well as brand names.

MUTUAL RECOGNITION PROCEDURE (MRP)

Mutual Recognition Procedure is one of two routes currently available for authorizing medicinal products for marketing in more than one country of the European Union.

The MRP is available for most conventional medicines and consists of the marketing authorization granted in one EU Member States being recognized as valid in other Member States upon request. The [EMA](#) serves as arbiter in case of disputes between the concerned parties over the application.



NEW DRUG APPLICATION (NDA)

When the sponsor of a new [drug](#) believes that enough evidence on the drug's safety and effectiveness has been obtained to meet the FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics.

If the NDA is approved, the product may be marketed in the US. For internal tracking purposes, all NDAs are assigned an NDA number.

ORANGE BOOK

The FDA's list of Approved Drug Products with Therapeutic Equivalences is commonly referred to as "The Orange Book." The FDA's official publication, it covers, among other things, approved generic, dose form dossiers, non-antibiotic [patent](#) expiries and Waxman-Hatch extension information for pharmaceuticals in the US.

The Orange Book is linked to Newport's proprietary intelligence on [API](#) manufacturing worldwide, patent data and [DMF](#) and AADA data from the FDA as part of NMLAdvanced.

ORGANISATION AFRICAINE DE LA PROPRIETE INTELLECTUELLE (OAPI)

A patent application organization comprising: Benin, Burkina Faso, Cameroon, Central Africa, Chad, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo.

PATENT

A patent is a temporary monopoly given by law to an inventor which allows the inventor to prevent others from exploiting the invention. In return, the inventor must make a full disclosure of the invention. The disclosure, which is a patent, must be such that a person skilled in the art would be able to work the invention.

Patent laws were originally created to provide inventors with an incentive to create new inventions by giving them temporary protection from competition. Today, the patent protection period gives inventors the opportunity to recoup their R&D investments in new products either by direct manufacture and sale or by licensing.

PATENT FAMILY

A group of patents claiming, as far as local laws allow, the same invention (same patent) in different countries.

PATENTEE

The patent holder. The name of the company, not the name of the person who filed the patent. The corporation is also identified in cases where there is a different parent company.

PCT

Patent Cooperation Treaty.

PRIORITY

The initial patent application, usually in the country of the invention, establishes the priority date (the date from which the invention is taken to be novel) and the priority number (the local application number) of the invention.

PRODUCT FAMILY

This information is intended to imply that either a trivial chemical processing relationship or a late stage intermediate/final product relationship exist between products within a product family.

Different salts of a specific product are considered to be within the same product family, ie. erythromycin estolate is in the same product family as erythromycin palmitate since they are both readily produced from erythromycin.

This information serves to identify sources of material that are likely to have the capability of supplying or producing products even if they are not currently producing the specified product.

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

The SmPC is a full, official description of a pharmaceutical product, which lists the name of the active substance, its composition, uses, dosages, pharmaceutical forms, and known adverse reactions, amongst other information.

The SmPC is the basis of information for health professionals on how to use the medicinal product safely and effectively. The condensed version provided to patients with the medicine in the form of a "patient information leaflet" (PIL) must be written in language that is easily understood by non-professionals.

SUPPLEMENTARY PROTECTION CERTIFICATE (SPC)

SPCs were introduced by the EU, and provide up to five years' protection from the date of patent expiry, up to a maximum of 15 years from the date of marketing authorization, for products, processes and methods of use.

Applications for SPCs must be made to the authority which granted the [patent](#) within six months of marketing authorization being granted (or within six months of a patent being granted when authorization precedes the grant of a patent).



THERAPEUTIC CLASS

A system for grouping pharmaceuticals based on similar therapeutic effect. A large number of distinct classifications have been compiled.

Two classifications are utilized: the Therapeutic category assigned by the Merck Index (based on the [USAN](#) assignment) and the Anatomical Therapeutic classification based on the European Pharmaceutical Market Research Association (EPHRA) Anatomical classification, which organizes therapeutic categories in a hierarchy.

THERAPEUTIC EQUIVALENCY CODE

The coding system developed by Thomson Reuters for therapeutic equivalence, designed to allow users to quickly determine if the FDA has evaluated a particular product as therapeutically equivalent to an approved product and to provide some information on the basis of this comparison. In the most common example, a generic drug is evaluated to determine equivalence to an approved branded drug.

Therapeutic equivalence codes consist of two letters. Products that are considered to be therapeutically equivalent are given the "A" designation as their first letter, while those considered not therapeutically equivalent are given the "B" designation. Codes AA, AN, AO, AP, and AT indicate no known bioequivalence problems, while the designation AB indicates that actual or potential bioequivalence problems were resolved. Codes BC, BD, BE, etc all indicate non-equivalence.

The AB rating is common for generic drugs where a paragraph IV filing is used to circumvent a certain innovator patent, and the innovator then challenges this new formulation on the grounds of non-bioequivalence. Once bioequivalence is demonstrated to the FDA, the generic would receive an AB rating.

TRIPS

Trade Related aspects of Intellectual Property Rights. The TRIPs agreement sets standards of protection and addresses enforcement procedures for intellectual property (IP) rights of [WTO](#) member countries.

Major provisions include: patent protection for pharmaceutical products; pharmaceutical patent protection of 20 years from the date of filing; limitations on compulsory licensing and a ban on specific compulsory licensing requirements for certain technologies; grant of patents is not dependent on local manufacture.

Countries which did not provide product patent protection at January 1 1995 must provide: a means for filing product patent applications; an exclusive marketing right of up to five years.

Developed countries have one year to incorporate the agreement into national law, developing countries have five years (10 years for product patents if they didn't

provide product patents by January 1 1995), and the least developed countries have 11 years.

USAN

United States Adopted Names. The official standard for generic names in the USA.

VOIDED CERTIFICATES

See [Certificates of Suitability \(CEP\)](#).

WAXMAN-HATCH ACT

The Patent Term Restoration and Price Competition Act passed by the US in 1984. Congressman Waxman of California and Senator Hatch of Utah were key architects of this historic piece of compromise legislation between the brand name and [generic drug](#) industries.

The Waxman-Hatch Act provided the brand name industry with a period of marketing exclusivity of up to five years to compensate for the extended period of FDA review of a [New Drug Application \(NDA\)](#). In return, [drugs](#) coming off [patent](#) were eligible for a simpler, quicker FDA review process involving submission of an [Abbreviated New Drug Application \(ANDA\)](#).

Waxman-Hatch provided for marketing exclusivity periods for non-antibiotic and non-biological products. For patent extensions under the Act, which was enacted September 24 1984, the patent-holder can apply to have the term of a patent extended for up to five years, up to a maximum of 14 years from NDA approval.

The actual extension period is based on the time taken by the regulatory review after the grant of the patent (half of the testing period plus the full NDA approval period): the extension period may be reduced if some of the time lost during this period is considered to be due to the patent-holder. The patent-holder may choose which patent (product, process or use) on a product is to be extended, but a patent may be extended only once.

WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

A specialized agency of the United Nations (UN) with responsibility for promoting the protection of intellectual property and for administering a number of international treaties, including the Paris Convention. It provides services for the international registration and filing of patents and trademarks, and facilitates the settlement of intellectual property disputes.

WIPO is responsible for the revision of the various treaties which it administers. It also prepares new treaties and conducts studies on intellectual property issues. A substantial training and advisory program is carried out for the benefit of developing countries.



WORLD TRADE ORGANIZATION (WTO)

Established on 1 January 1995 as the successor to [GATT](#). While GATT was applied on a 'provisional basis', WTO commitments are full and permanent for the entire membership. Three councils have been set up by the WTO to oversee trade in the following areas: goods, services and trade-related aspects of intellectual property rights (the [TRIPs](#) Agreement). The GATT 1994 Agreement forms an integral part of the WTO Agreement.

WORLD TRADE ORGANIZATION AGREEMENT

The World Trade Organization Agreement, also known as the Marrakesh Accord, is a trade agreement signed on 15th April 1994 at the end of the Uruguay Round of [GATT](#) negotiations.

Major provisions affecting pharmaceuticals include: the elimination of international trade tariffs on all pharmaceuticals (including bulk pharmaceuticals, intermediaries and finished formulations) and medical equipment; and improved intellectual property rights, under the Trade Related aspects of Intellectual Property Rights ([TRIPs](#)) agreement. The Agreement was implemented from January 1995.

GOVERNMENTAL / REGULATORY

[CDER Home Page](#)

[European Medicines Agency](#)

[FDA Home Page](#)

[Heads Of The European Agencies](#)

[U.S. Patent And Trademark Office](#)

ORGANIZATIONS

[American Chemical Society \(ACS\)](#)

[Canadian Generic Pharmaceutical Association \(CGPA\)](#)

[Drug Information Association \(DIA\)](#)

[Drug, Chemical, & Associated Technologies Association \(DCAT\)](#)

[European Generics Medicines Association \(EGA\)](#)

[Generic Pharmaceutical Association \(GPHA\)](#)

[International Pharmaceutical Federation \(FIP\)](#)

[Pharmaceutical Research & Manufacturers Of America \(PHRMA\)](#)

[Regulatory Affairs Professionals Society \(RAPS\)](#)

[Society Of Competitive Intelligence Professionals \(SCIP\)](#)

[Synthetic Organic Chemical Manufacturers Association \(SOCMA\)](#)

[U.S. Pharmacopeia \(USP\)](#)

TRADE SHOWS & CONFERENCES

[CPHI Worldwide](#)

[DCAT Week](#)

[EGA Meetings](#)

[GPHA Meetings](#)

[IGPA Annual Conference](#)

[INFORMEX](#)

[Marcus Evans](#)

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