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100% Effective Natural Hormone Treatment
Menopause, Andropause And Other Hormone Imbalances
Impair Healthy Healing In People Over The Age Of 30!

How New Acne Drugs Are Developed

By Doug Smith

The U.S. Food and Drug Administration (FDA) states its purpose in the following mission statement:

"The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."

In 2005 the FDA provided a public draft guidance document to the pharmaceutical industry on the development of drugs to treat acne vulgaris, or acne. The draft guidance document contains the FDA's current thinking on the development of acne drugs and the methods that should be used.

Some of the guidance document information is summarized below. At the time of this writing the FDA document had not been finalized.

Types of Acne Lesions

The two major types of acne lesions are classified as non-inflammatory and inflammatory. Non-inflammatory acne lesions are more commonly known as whiteheads and blackheads. Inflammatory acne lesions include papules and pustules and are more deeply seated in the skin than the non-inflammatory lesions.

How Acne Severity Is Rated

Currently there is no standardized method for rating the severity of acne outbreaks. Several methods have been proposed, but each has its difficulties. A sample scale for rating acne severity is summarized below, from least to most severe:

0 Clear skin with no inflammatory or non-inflammatory lesions

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1 Almost clear; rare non-inflammatory lesions with no more than one small inflammatory lesion

2 Mild severity; greater than Grade 1; some non-inflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions)

3 Moderate severity; greater than Grade 2; up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion

4* Severe; greater than Grade 3; up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

(* worsening beyond Grade 4 is possible).

Acne Drug Treatment Study Groups

Acne drug test groups should be large enough to be statistically significant so that any claims of success and safety can be supported. Test patients are usually recruited during their most severe acne breakouts.

Acne drug trials are recommended to be randomized, blinded, multicenter trials, and other requirements will also apply. A control or placebo group should be utilized.

Furthermore, those doing testing should recruit test populations that are representative of the age, race, gender, and geographic location of acne patients in the United States.

Determining The Success Of Acne Drug Treatments

Acne severity is rated at the beginning and end of every test. Photographic evidence and/or lesion counts may also be taken. It is proposed to measure the success of acne medications as either a success or a failure, based on one of these two methods of measuring success:

1. Success meaning a rating of clear skin or almost clear (severity rating 0 or 1) within the test period;
or

2. Success meaning an improvement of 2 severity grades within the test period. Under this definition, a successful test subject would have a severity improvement from 4 to 2 within the test period, as an example.

The Final Decision On New Acne Drugs

Several phases of testing are recommended for proposed acne drugs. Studies must be designed to account for effects such as test dropouts. Rigorous data analysis must be performed in conformance with FDA regulations. Only acne drug test data that has been validated and undergone quality assurance testing should be submitted to the FDA for approval.

How New Acne Drugs Are Developed

Only through a rigorous and tightly–controlled testing and analysis procedure, followed by FDA approval, can new acne drugs be made available to the public.

The resource link below contains free information on the best ways to utilize FDA–approved prescription and over the counter acne drugs and treatments.

Source: Guidance for Industry, Acne Vulgaris: Developing Drugs for Treatment, DRAFT GUIDANCE, U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER), September 2005, Clinical/Medical.

Want to get rid of your acne fast? Learn how from our free library of acne cures, acne treatments, and acne skin care advice at

<http://acne.superhomeremedies.com>

How to outsmart zits

By Naweko San–Joyz

How to outsmart zits by Naweko San–Joyz

In 2001, after comparing over 250 studies and 150 drugs, a team at Johns Hopkins Children's Center still has no clue as to how to successfully treat acne. With this lineup of intelligence failing to cure acne, how can any average Jane expect to free herself from a zit affliction? Simple; crack the code of your zits.

An effective acne treatment has remained elusive because the deeper meanings behind the information–packed pimples are too often neglected or unexamined, until now.

"Listen to the messages of your zits", proclaims Naweko San–Joyz, author of *Acne Messages: Crack the code of your zits and say goodbye to acne*. Zits are smart and full of knowledge about you and your lifestyle. Those pimples on your face act as little messengers from the body to suggest beneficial changes to your lifestyle and areas of your life to which you should pay more attention.

Acne Messages guides the exacerbated acne sufferer to find out exactly what causes their unique case of acne. This is the shortcoming of most acne prescriptions and creams; they treat acne as a target as opposed to probing into what emotional, physical, psychological and or nutritional needs set off the acne trigger.

Once you decode you zit, the zit will reveal a wealth of practical information about you. For example, how well you cope with stress, whether or not your specific nutritional needs are being met, if your personal goals are being met, if your organs are functioning at optimum levels, and whether or not your self esteem is balanced are just of sample of the revelations communicated by zits. Using ancient wisdom and modern science San–Joyz helps people with acne pinpoint the root cause of their unique case of acne.

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Acne Messages is designed for people with acne who can find no relief with drugs, special diets, or creams alone.

Do you let your zits tell you at least these five things about yourself before you pop it, slather it with creams, or ingest some acne wonder drug? If not, this could be why you are one of the 17 million people in the United States still coping with acne.

Read Acne Messages, decode the messages of your zits and say goodbye to acne. You can own Acne Messages just \$14.99 plus shipping and handling.

<http://www.noixia.com> Naweko San-Joyz is a graduate of Stanford University. She recently published

"Acne Messages: Crack the code of your zits and say goodbye to acne". To challenge and verify her research, San-Joyz trains for figure competitions. She currently writes health articles from her home in San Diego.



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