DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–204]

RIN 1117–AA55

Interpretation of Listing of ''Tetrahydrocannabinols'' in Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Interpretive rule.

SUMMARY: For the reasons provided herein, the Drug Enforcement Administration (DEA) interprets the Controlled Substances Act (CSA) and DEA regulations to declare any product that contains any amount of tetrahydrocannabinols (THC) to be a schedule I controlled substance, even if such product is made from portions of the cannabis plant that are excluded from the CSA definition of ''marihuana.'' Consistent with this interpretation, DEA is publishing today a proposed rule in a separate Federal Register document that immediately follows this interpretive rule. The proposed rule proposes to revise the wording of the DEA regulations to make clear that the listing of THC in schedule I refers to both natural and synthetic THC. In a third **Federal Register** document being published today (following the proposed rule), DEA is issuing an interim rule, which exempts from control certain industrial products, processed plant materials, and animal feed mixtures made from those portions of the cannabis plant that are excluded from the definition of marijuana, to the extent such products, plant materials, and feed mixtures contain THC but are not used, or intended for use, for human consumption. The interim rule also provides a 120-day grace period for persons to dispose of existing inventories of THC-containing ''hemp'' products that are not exempted from control.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Why Is DEA Issuing This Interpretive Rule?

Over the past several months, DEA has received numerous public inquiries regarding the interpretation of the CSA with respect to certain products made from plants of the genus Cannabis (hereafter, ''cannabis plant''). These inquiries have raised the following question: If a product contains THC but is made from a portion of the cannabis plant that is excluded from the CSA definition of marijuana, is such product a controlled substance? This document answers this question and provides the public with the in-depth legal analysis that DEA has undertaken.

Legal Analysis

A. Relevant Statutory Provisions

Under the CSA, marijuana is defined as follows:

> The term ''marihuana'' [1] means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

21 U.S.C. 802(16). As the second sentence of this definition indicates, Congress expressly exempted certain portions of the cannabis plant from the definition of marijuana. At the same time, however, Congress expressly declared in the scheduling provisions of the CSA that ''any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols [THC]'' is a schedule I controlled substance. 21 U.S.C. § 812(c), schedule I(c)(17).

Given the foregoing provisions of the CSA, several persons have recently asked DEA about the legal status of products marketed in the United States that are made from portions of the cannabis plant that are excluded from the definition of marijuana. Such products include, among other things, certain types of paper, clothing, bird seed, food, beverages, shampoos, and body lotions. Often, such products are labeled or advertised as being made from ''hemp.'' (Some members of the public refer to these as ''hemp'' products.) In some cases, the labeling indicates that the products contain a certain percentage of THC. Given the recent increase in marketing of these so-called ''hemp'' products in the United States, and given that many such products have recently been determined to contain THC, DEA has repeatedly been asked in recent months whether the THC content of such products renders them controlled substances despite the fact that they are reportedly made from portions of the cannabis plant that are excluded from the definition of marijuana.

In DEA's view, the answer lies in the plain language of the CSA, which states that ''any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols'' is a schedule I controlled substance. The CSA does not state that any material, compound, mixture, or preparation containing THC is only a controlled substance if it fits within the definition of marijuana.

Several members of the public who have corresponded with DEA disagree with the above interpretation of the CSA. Some have contended that classifying what they term ''hemp'' products as controlled substances is contrary to the history of the federal drug laws, DEA's own regulations, and reported court decisions. In light of such comments from the public, set forth below is a detailed analysis of pertinent legal authorities.

B. Historical Development of the Law

Congress' definition of marijuana has remained unchanged since 1937. The definition that appears in the CSA today is identical to the definition that was contained in the Marihuana Tax Act of 1937. Congress carried this definition forward when it enacted the CSA in 1970. (The CSA repealed and superseded the Marihuana Tax Act.)

The question presented here is not answered by the legislative history of the CSA. The 1970 Congress seems to have adopted the definition of marijuana from the 1937 Marihuana Tax Act without reported discussion. In contrast, the legislative history of the Marihuana Tax Act contains substantial discussion of the definition of marijuana. The Senate Report to the 1937 Act states:

> The term ''marihuana'' is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present. The testimony before the committee showed definitely that neither the mature stalk of the hemp plant nor the fiber produced therefrom contains any drug, narcotic, or harmful property whatsoever and because of that fact the fiber and mature stalk have been exempted from the operation of law.

S. Rep. No. 900, 75th Cong., 1st Sess., at 4 (1937).

The foregoing legislative history was reiterated by the United States Court of Appeals for the District of Columbia Circuit in a 1975 case, *United States* v. *Walton,* 514 F.2d 201. The court stated:

> Looking at the legislative history of [the Marihuana Tax Act of 1937], we find that the

[1] ''Marihuana'' is the spelling used in the CSA. In this document, the common spelling ''marijuana'' is used, except when directly quoting the CSA or citing the ''Marihuana Tax Act of 1937.''

definition of marijuana was intended to include those parts of marijuana which contain THC and to exclude those parts which do not. * * * The legislative history is absolutely clear that Congress meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC.

Id. at 203–204.

Thus, it is evident that the 1937 Congress exempted certain portions of the cannabis plant from the definition of marijuana based on the assumption (now refuted) that such portions of the plant contain none of the psychoactive component now known as THC.[2] Although the 1970 Congress did not revisit this issue when it carried forward the 1937 definition of marijuana, it did separately specify that ''any material, compound, mixture, or preparation, which contains any quantity of * * * ''Tetrahydrocannabinols'' is a schedule I controlled substance. This is consistent with the conclusion of the Court of Appeals in Walton that, in enacting both the 1937 Act and the CSA, ''Congress meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC.''

It cannot be assumed (as some members of the public have asserted in recent correspondence with DEA) that because Congress adopted the 1937 definition of marijuana when it enacted the CSA, it intended to control marijuana in precisely the same manner as under the Marihuana Tax Act. As the United States Court of Appeals for the First Circuit recently stated: ''While in 1937 Congress had indicated in legislative history that production for industrial uses would be protected (primarily by a relatively low tax), we can find no indication that Congress in 1970 gave any thought to how its new statutory scheme would affect such production.'' *New Hampshire Hemp Council, Inc.* v. *Marshall,* 203 F.3d 1 (1st Cir. 2000) (citations omitted). The First Circuit further explained that basic differences between the 1937 Act and the CSA disallow interpreting the two acts in the same way:

> Congress' main vehicle for protecting industrial-use plant production in 1937 was not its basic definition of ''marijuana,'' which included plants ultimately destined for industrial use; it was the complex scheme of differential tax rates and other requirements for transfers. That is the regime that was drastically modified in 1970 in favor of a broad criminal ban (subject only to federal licensing), a ban which read literally embraces production of cannabis plants regardless of use.
>
> The possibility remains that Congress would not have adopted the 1970 statute in its present form if it had been aware of the effect on cultivation of plants for industrial uses. But that is only a possibility and not a basis for reading the new statute contrary to its literal language, at least absent a clear indication that Congress intended to protect plant production for industrial use as it existed under the prior tax statute. Nor, given Congress' enlargement of drug crimes and penalties in recent years, would one bank on its adoption of an exception strongly opposed by the DEA as a threatened loophole in the ban on illegal drugs.

Id. at 7 (footnote and citation omitted). Thus, industrial uses of marijuana that were permitted under the 1937 Tax Act are not necessarily permissible under the CSA, even though the definition of marijuana has remained the same in both acts.

One might reasonably ask: Why would Congress exempt certain portions of the cannabis plant from the CSA definition of marijuana if such portions would nonetheless be subject to CSA control to the extent they contain THC? The answer now seems clear. As indicated above, the 1970 Congress did not address the possibility that portions of the cannabis plant excluded from the definition of marijuana might contain THC.

C. Control of Natural and Synthetic THC

Some members of the public who have corresponded with DEA have expressed the view that the listing of THC in schedule I of the CSA applies only to synthetic THC, rather than natural THC. (For purposes of this document, ''natural THC'' means THC found in nature in the cannabis plant, as opposed to THC synthesized by humans.) Based on this supposition, some have contended that the THC content of ''hemp'' products is irrelevant because only synthetic THC (not natural THC) is controlled under the CSA. As explained below, DEA rejects this contention because it is DEA's interpretation that the listing of THC in schedule I includes both natural and synthetic THC.

1. Listing of THC in the CSA

When Congress established the initial schedules of controlled substances in 1970, it simply listed ''Tetrahydrocannabinols'' in schedule I. The CSA makes no mention of synthetic versus natural THC. Furthermore, the commonly understood meaning of ''Tetrahydrocannabinols'' includes both natural THC and synthetic THC, since ''Tetrahydrocannabinols'' is simply a name that refers collectively to a category of chemicals—regardless of whether such chemicals occur in nature or are synthesized in a laboratory. For example, Merriam-Webster's Collegiate Dictionary (10th ed. 1999) defines ''THC'' as ''a physiologically active chemical $C_{21}H_{30}O_2$ from hemp plant resin that is the chief intoxicant in marijuana—called also tetrahydrocannabinol;'' this definition does not mention synthetic THC.

2. Listing of THC in the DEA Regulations

In the DEA regulations, THC is listed in schedule I as follows:

Tetrahydrocannabinols 7370

Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

Δ^1 cis or trans tetrahydrocannabinol, and their optical isomers

Δ^6 cis or trans tetrahydrocannabinol, and their optical isomers

$\Delta^{3,4}$ cis or trans tetrahydrocannabinol, and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

21 CFR 1308.11(d)(27). DEA interprets this regulation at face value. The first line—''Tetrahydrocannabinols''—refers to all forms of THC (natural or synthetic), while the subsequent lines refer to synthetic equivalents of the substances contained in the cannabis plant and synthetic substances with similar chemical structure and pharmacological activity. That the regulation refers specifically to certain synthetic equivalents of THC does not

[2] The technology used for chemical analysis has improved significantly since 1937. Using advanced methods of testing that are currently available, the analysis of all portions of today's cannabis plant, including those portions that are excluded from the definition of marijuana, will result in the identification of some amounts of THC within the structure of all portions of the plant. Additional amounts of THC might also be detected on the surface of those portions of the plant excluded from the definition of marijuana due to resin or particulate matter from other portions of the plant that adhered to the excluded portions during the harvesting process.

Some members of the public who have corresponded with DEA correctly point out that the legislative history of the 1937 Act contains testimony from witnesses who believed that some portions of the cannabis plant that were being excluded from the definition of marijuana did contain small amounts of the psychoactive drug. Other witnesses who appeared before the 1937 Congress testified to the contrary—that the portions of the plant that were being excluded from the definition of marijuana contained none of the psychoactive drug. In the final analysis, the Senate concluded (as quoted above) that the 1937 Act defined marijuana ''so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present.''

mean that natural THC is excluded. The regulation does not state, for example: ''Tetrahydrocannabinols, meaning only synthetic equivalents. * * *''

To better understand this regulation, it is helpful to examine the historical control of THC under federal law.

3. Historical Control of THC Under Federal Law

Natural THC found in marijuana has been controlled, at least implicitly, under federal law since 1937. As stated above, under the Marihuana Tax Act of 1937, marijuana was defined exactly as it is now under the CSA—to include, among other things, any ''compound, manufacture, salt, derivative, mixture, or preparation of'' the cannabis plant. This definition included natural THC (to the extent such THC was contained in, or derived from, those portions of the cannabis plant included in the definition of marijuana). Thus, from 1937 until 1971 (the year the CSA became effective and the Marihuana Tax Act was repealed), such natural THC was federally controlled under the Marihuana Tax Act.

Synthetic THC, however, was not controlled under the 1937 Marihuana Tax Act since it did not fit within the Act's definition of marijuana. Nor were there any other federal drug laws in existence in 1937 that controlled synthetic hallucinogenic substances. Moreover, there was no reason in 1937 to expressly control THC (natural or synthetic) since this chemical had not been isolated in 1937 and it was not synthesized in the laboratory until 1964. In the late 1960s, when synthetic THC began showing up in the illicit market, federal officials concluded that federal control over the drug was necessary to prevent abuse. At that time, however (approximately three years before the enactment of the CSA), the federal laws governing drugs of abuse were not unified into a single act as they are now under the CSA. Marijuana and its derivatives were controlled under the Marihuana Tax Act; narcotics were controlled under a variety of acts, including the Harrison Narcotics Act of 1914; and what were termed ''depressant and stimulant drugs'' (which included some hallucinogenic substances) were controlled under the Drug Abuse Control Amendments of 1965 (DACA), which were part of the Food, Drug, and Cosmetic Act.

Because synthetic THC is a synthetic hallucinogenic substance, any federal control of the drug in 1968 could only be accomplished pursuant to DACA. Accordingly, the Bureau of Narcotics and Dangerous Drugs (BNDD, which was DEA's predecessor) promulgated a regulation, effective September 21, 1968, listing synthetic THC under DACA. This 1968 BNDD regulation was identical to the current listing of THC in the DEA regulations, except that the general reference to ''Tetrahydrocannabinols'' was absent. Thus, the 1968 regulation was expressly limited to synthetic THC (and synthetic equivalents thereof). This was because DACA prohibited BNDD from promulgating a regulation that would list under DACA any substance included in the definition of marijuana under the Marihuana Tax Act of 1937. In other words, if a drug was controlled under the Marihuana Tax Act, it could not also be controlled under DACA. Since natural THC (derived from marijuana) fit within the definition of marijuana and was thereby controlled under the Marihuana Tax Act, the BNDD regulation listing THC had to exclude such natural THC. Therefore, the BNDD regulation listing THC under DACA was limited to the synthetic form.

Thus, during the brief period from September 21, 1968, until May 1, 1971 (the effective date of the CSA), natural and synthetic THC were separately controlled under distinct federal acts. Natural THC (as a derivative of marijuana) was controlled under the Marihuana Tax Act of 1937, while synthetic THC was controlled under DACA.

When Congress enacted the CSA in 1970, one of its aims was to unify what had been the ''plethora of legislation'' controlling narcotics and dangerous drugs into ''one piece of legislation.'' H. Rep. No. 91–1444, 1970 U.S.C.C.A.N. 4566, 4571. One result was that, following the enactment of the CSA, THC no longer had to be separately categorized into ''natural'' versus ''synthetic'' in order to maintain the Congressionally mandated separation between drugs controlled under DACA and those controlled under the Marihuana Tax Act. Thus, Congress was able to list ''Tetrahydrocannabinols'' in schedule I without having to distinguish between natural and synthetic. Likewise, the first regulations implementing the CSA (the 1971 BNDD regulations) did not simply carry forward, without change, the prior regulation that listed only ''synthetic'' THC (as was required under DACA). Rather, BNDD added the general term ''Tetrahydrocannabinols'' to the beginning of the listing, above the references to ''synthetic equivalents,'' since the regulation no longer had to be limited to synthetic THC.

Thus, it is DEA's interpretation that the listing of THC in schedule I of the CSA and DEA regulations has always included both natural and synthetic THC.

4. Case Law Addressing Natural and Synthetic THC

It appears that no court has ever undertaken the foregoing extensive analysis of the control of natural and synthetic THC. Further, the few reported cases that have addressed the issue reach differing conclusions.

The first case to address the issue was United States v. Wuco, 535 F.2d 1200 (9th Cir. 1976), where the defendants were initially charged with trafficking in marijuana. When the defense indicated that they would argue the ''species defense'' (i.e., that the CSA only prohibits trafficking in ''Cannabis sativa L.''—not the supposedly other variety of cannabis with which defendants ''were caught red-handed''), the United States Attorney's Office sought to preclude this defense by filing a superseding indictment that charged defendants with trafficking in ''marijuana, a substance containing * * * tetrahydrocannabinol * * *, a schedule I controlled substance.'' Defendants were convicted of the latter charge and, on appeal, sought to reverse their conviction on the ground that this charge required the government to prove ''that the substance they possessed contained synthetic THC.'' For reasons that are not revealed in the court's opinion, the United States Attorney's Office ''conceded'' on appeal that the listing of ''Tetrahydrocannabinols'' in schedule I was limited to synthetic THC. The court agreed with this ''concession'' without explanation. The Wuco opinion contains no analysis of the CSA, DEA regulations, or legislative history. The opinion simply indicates that the court and the government agreed for purposes of that case that the listing of ''Tetrahydrocannabinols'' in schedule I meant only synthetic THC.

United States v. *Lochan,* 674 F.2d 960 (1st Cir. 1982), was another case in which the defendant was charged with, and convicted of, trafficking in ''tetrahydrocannabinols'' (in this case, hashish)—rather than ''marihuana''. Defendant argued on appeal that the government was required to prove that the hashish contained THC. The appeals court disagreed, indicating that it was sufficient for the government to prove ''that the material was in fact hashish.'' In addressing this issue, the court stated: ''Hashish is a schedule I substance if it contains tetrahydrocannabinols (THC), 21 U.S.C. 812, Schedule I (c)(17), which is the 'active ingredient' in hashish.'' This statement by the court is consistent with

the view that the listing of ''Tetrahydrocannabinols'' in schedule I does include natural (not merely synthetic) THC.

United States v. *McMahon,* 861 F.2d 8 (1st Cir. 1988) was another case in which the indictment charged the defendant with trafficking in ''hashish, a substance containing tetrahydrocannabinol, a Schedule I controlled substance.'' Based on this charge, the defendant contended that the government was required to prove the presence of THC in order to convict. The court upheld the conviction, ruling that ''the government is not required to prove that the substance contained THC, organic or synthetic; [i]t merely has to prove * * * that the substance was hashish and thus a derivative of marijuana, a Schedule I controlled substance.'' In attempting to explain this ruling, the court stated that ''the substance referred to in Schedule I(c)(17) is synthetic, not organic, THC.'' As support for this statement, the court cited Wuco and pointed to the separate listings of ''Marihuana'' and ''Tetrahydrocannabinols'' in schedule I of the DEA regulations. The court referred to the DEA regulations as ''describing THCs listed in schedule I as '[s]ynthetic equivalents of substances contained in the plant . * * * ''''

In DEA's view, the McMahon court erred in suggesting that the separate listings of ''Marihuana'' and ''Tetrahydrocannabinols'' in schedule I are mutually exclusive. Congress gave no indication in the CSA that there can be no overlap between separate listings in a particular schedule. An example serves to illustrate. In schedule I of both the CSA and DEA regulations, ''peyote'' is listed separately from ''mescaline''. Mescaline is to peyote what THC is to marijuana: the former is the psychoactive chemical component of the plant, while the latter is the plant itself (including derivatives thereof). Both natural and synthetic mescaline are known to exist. Yet, the fact that natural mescaline falls under the listing of ''peyote'' (as an extract, compound, derivative or preparation of such plant—see 21 CFR 1308.11(d)(22)) does not mean that the separate listing of ''mescaline'' refers only to the synthetic form. On the contrary, the listing of ''mescaline'' refers to the chemical in any form (natural or synthetic).

Moreover, the McMahon court acknowledged that its interpretation of ''Tetrahydrocannabinols'' appears inconsistent with that of the Lochan court. See 861 F.2d at 11 n.1. To resolve this apparent discrepancy between these two First Circuit cases, the McMahon court suggested that it may be possible that natural THC fits within the listing of both ''Tetrahydrocannabinols'' and ''Marihuana'' in schedule I. Id. In doing so, the McMahon court effectively acknowledged that the listing of THC in schedule I is not limited to synthetic THC.

Because the foregoing three cases arrive at no consensus about the issue of natural versus synthetic THC, and because none of the cases contains an in-depth study of the control of THC, these decisions fail to resolve the issue here. More instructive is the Walton decision (discussed earlier), which points out that THC content was of paramount concern to Congress in deciding how to control marijuana.

Conclusion

By stating that ''any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols'' is a schedule I controlled substance, the plain language of the CSA leads to the conclusion that all products containing any amount of THC are schedule I controlled substances. The legislative history supports this conclusion by revealing that Congress wrote the definition of marijuana intending to control all parts of the cannabis plant that were believed to contain THC. When the CSA was enacted, the implementing regulations did not simply adopt, verbatim, the prior regulations that were expressly limited to synthetic forms of THC. Rather, the word ''Tetrahydrocannabinols'' was inserted in the regulations at the top of the listing, thereby including all forms of THC (natural and synthetic). DEA therefore interprets the CSA and DEA regulations such that any product that contains any amount of THC is a schedule I controlled substance, even if such product is made from portions of the cannabis plant that are excluded from the definition of marijuana.

DEA recognizes that this interpretive rule, standing alone, would effectively prohibit the use of an assortment of industrial products made from the cannabis plant (such as certain paper products, fiber, rope, and animal feed) that Congress intended to allow under the 1937 Marihuana Tax Act. Although the intent of the now-repealed 1937 Act is no longer controlling, DEA is issuing today, in a separate **Federal Register** document that accompanies this document, an interim rule that will except from CSA control the types of industrial products that were allowed under the 1937 Act, provided such products do not cause THC to enter the human body. See [insert **Federal Register** cite for interim rule]. As explained further in the interim rule, all other products made from any of the excluded portions of the cannabis plant (such as edible ''hemp'' products) remain controlled substances if they cause THC to enter the human body.

Also as set forth in the interim rule, a 120-day grace period is being provided for persons to dispose of existing inventories of THC-containing ''hemp'' products that are not exempted from control.

Regulatory Certifications

This document is an interpretive rule. It is not a proposed rule, general notice of which the agency must publish in accordance with the Administrative Procedure Act. See 5 U.S.C. 553. Therefore, the following provisions, which require the agency to include regulatory certifications in proposed rules, are not applicable to this document: Regulatory Flexibility Act (5 U.S.C. 601–612); Executive Order 12988 (civil justice reform); Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538); and Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801–808). All of the foregoing certification provisions are addressed, however, in the proposed rule that accompanies this interpretive rule. See [insert **Federal Register** cite for proposed rule].

Executive Order 12866

This interpretive rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, § 1(b), Principles of Regulation. This rule has been determined to be a ''significant regulatory action'' under Executive Order 12866, § 3(f). Accordingly, this interpretive rule has been reviewed by the Office of Management and Budget for purposes of Executive Order 12866.

Executive Order 13132

This interpretive rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state or diminish the power of any state to enforce its own laws. Accordingly, this interpretive rule does not have federalism implications warranting the application of Executive Order 13132.

Paperwork Reduction Act of 1995

This interpretive rule does not involve collection of information within the meaning of the Paperwork Reduction Act of 1995.

Plain Language

In writing this interpretive rule, DEA has attempted to use plain language in

an easy-to-read manner, consistent with the June 1, 1998 directive of the President. See 63 FR 31885. If you have any suggestions to make this document more clear, call or write Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Washington, D.C. 20537; telephone: (202) 307–7297.

Dated: October 2, 2001.

Asa Hutchinson,

Administrator.

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